EXHIBIT 1

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE) PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:
All Cases

MAGISTRATE JUDGE HANNA

MEMORANDUM OPINION AND RULING

I. Introduction

This multidistrict litigation arises from product liability claims against the manufacturer and marketer of Actos® and other drugs containing pioglitazone. Currently pending before the Court is the "Plaintiffs' Steering Committee's ("PSC") Spoliation and Rule 37 Motion for Sanctions" [Doc. 3484].[1] In its motion, the PSC argues the Takeda entities (defendants Takeda Pharmaceuticals U.S.A., Inc., Takeda Development Center Americas, Inc. (f/k/a Takeda Global Research & Development Center, Inc.), Takeda Pharmaceutical Company, Ltd. ("TPC"), Takeda Pharmaceuticals America, Inc., Takeda California, Inc., Takeda Pharmaceuticals International, Inc., and Takeda Pharmaceuticals, LLC (collectively, Takeda)) intentionally destroyed documents relevant to the instant litigation in bad faith, resulting in prejudice to the plaintiffs. The PSC seeks a default judgment, or in the alternative, a combination sanction of cost-shifting, a fine, an adverse inference jury instruction, restoration of the deleted files, and attorneys' fees

[1] The Spoliation Motion was filed on October 1, 2013. Briefing on the motion was completed on November 5, 2013. During the following two months, this Court understood that counsel for both parties were engaged in voluntary negotiations in an effort to achieve an amicable resolution to the dispute presented in the Spoliation Motion. This Court used the intervening two month period to work up, address, and rule on a large number of pending motions (including *Daubert* motions, motions in limine, and summary judgment motions). All rulings on those motions were completed and filed by January 15, 2014. Shortly before the last of these numerous rulings was issued, this Court was informed that negotiations on the Spoliation Motion had ended without success, and this Court turned its attention to the Spoliation Motion.

and costs. Takeda filed a responsive brief on October 30, 2013 [Doc. 3530], and the PSC filed its Reply on November 6, 2013 [Doc. 3569].

The PSC urges separate, but overlapping, violations by Takeda: a violation of Rule 37 of the Federal Rules of Civil Procedure, and that "spoliation" occurred such that this Court should exercise its inherent powers and assess sanctions against Takeda. The Federal Rules of Civil Procedure governs the alleged violation of Fed.R.Civ.P. 37, whereas jurisprudence informs the inquiry of "spoliation." Within that jurisprudence, certain U.S. District Court cases, including the *Zubulake* line of cases, discussed below, have come to be accepted as particularly instructive on the issue of "spoliation."

Spoliation is generally defined within the applicable jurisprudence as "the destruction or significant alteration of evidence, or the failure to preserve property for another's use as evidence in pending or reasonably foreseeable litigation." *Zubulake v. UBS Warburg, LLC*, 229 F.R.D. 422, 430 (S.D.N.Y. 2004) (J. Scheindlin), *quoting West v. Goodyear Tire & Rubber Co.*, 167 F.3d 776, 779 (2nd Cir.1999). At issue in this case is, primarily, the destruction of electronic evidence.

The crux of the instant motion is the PSC's argument that Takeda destroyed relevant and beneficial evidence after it had a duty to preserve that evidence, and that the destruction of the evidence was done in bad faith, consequently, the plaintiffs are entitled to, among other sanctions, an adverse inference instruction for the jury. In response, Takeda argues it has in no way destroyed documents in bad faith, but rather, has maintained and produced a host of documents and has in place retention policies and procedures designed to safeguard information for litigation, and that these procedures were followed in this case. Takeda's argument focuses, primarily, upon its assertion that the reason it has been unable to produce certain responsive documents is that it did not reasonably anticipate *bladder* cancer litigation until July 2011, and therefore, it did not believe it had a duty to preserve evidence relating to *bladder* cancer, as to Takeda's drug, Actos, prior to that time and therefore, the broad litigation hold Takeda put in place in 2002, and "refreshed" thereafter, should not govern or apply. Thus, Takeda argues there are reasonable explanations for its failure to produce multiple documents that have been requested by the PSC. Both sides vehemently argue their positions, and an exhaustive review of the record has been made by this Court in an effort to determine what evidence was lost, and why, and the possible import, or lack thereof, of that evidence.

For the reasons that follow, this Court concludes relevant evidence was deleted by Takeda after the duty to preserve such evidence arose. The Court further finds, for the reasons that follow, the PSC has presented *prima facie* evidence that the evidence would have been both relevant and beneficial to the Plaintiffs' cases within this MDL and of bad faith on the part of Takeda. Takeda vehemently disputes the basis for such a finding, arguing the requisite intent does not exist. Consequently, at this juncture, on the eve of the first bellwether trial of this MDL, this Court makes the following findings, conclusions, and legal determinations.

II. Factual Background and Procedural History

A. Facts Relating to Discovery Requests

As a general matter, this case has progressed in an exceptional manner due to the continued and professional cooperation of the parties, aided by the Special Masters and with input of the magistrate judge, resulting in the resolution of most discovery issues and disputes without the need for formal court intervention. In the spirit of such cooperation, the PSC and Takeda agreed to certain discovery schedules within which Takeda would produce certain custodial files. The PSC, thereafter, separated its document requests into two categories: (1)

documents maintained by sales representatives working for Takeda; and (2) documents maintained by Takeda employees in the United States, Japan, and the European Union.

With respect to the first category of documents – documents maintained by sales representatives – the parties devised a system by which Takeda was to produce responsive documents. Under that system, on April 26, 2013, the PSC identified sales representatives whose files it felt were relevant to the Pilot Bellwether Program implemented by the Court, and both Takeda and the PSC agreed the requested production would be produced in "waves." The "first wave" was to include both e-mails and personnel files for fifteen (15) sales representatives and were to be produced no later than May 24, 2013. The "second wave" was to include the e-mails and personnel files of twenty (20) sales representatives and were to be produced no later than June 14, 2013. The "third wave" was to include both e-mails and personnel files of fifteen (15) sales representatives and were to be produced no later than June 21, 2013.

On May 24, 2013 – the deadline to produce "wave one" of the sales representatives' files – Takeda informed the PSC it did not have four (4) of the fifteen (15) files requested as those files no longer existed or could not be found. All of the files in this wave were the files of former employees who had left their employment with Takeda between 2001 and 2006. On May 31, 2013, the PSC asked Takeda to identify any other requested sales representatives' files that had been "destroyed." On June 3, 2013, Takeda identified two (2) sales representatives in "wave two" whose files had been "destroyed." On June 5, 2013, the PSC substituted six (6) additional sales representatives in place of the four representatives from "wave one" and the two representatives from "wave two" whose files had been "destroyed." On June 10, 2013, Takeda informed the PSC that three (3) of the six (6) newly substituted sales representatives' files were either "partially or completely destroyed."

As it had for the files of sales representatives, on March 14, 2013, the PSC identified certain Japanese employees whose files were sought. Again, as it had for the files of certain sales representatives, Takeda, thereafter, notified the PSC certain of the requested Japanese files had been "deleted." On May 22, 2013, Takeda sent an e-mail listing the files of certain Japanese employees and three (3) European employees that had been "deleted" upon the departure of these employees from the employ of Takeda between 2001 and 2011.

It is undisputed there are a total of forty-six (46) custodial files that cannot be located – or have not been produced - by Takeda.[2] The PSC alleges a number of these forty-six custodial files belonged to Takeda employees ranging from "company presidents to key officers," individuals argued to have had critical information regarding the development and marketing of Actos. The following custodial files of *Japanese Takeda* employees are missing:[3]

1. Mikihiko "Ken" Obayashi, Director, Pharmaceutical Development Division, who worked for Takeda Pharmaceutical Company Limited (a Japanese Takeda entity, hereinafter "TPC") from April 1, 1965 to February 1, 2001. Mr. Obayashi had this title from July 1992 until his retirement in 2001. According to the PSC, Takeda has located no files, documents, or e-mails for Mr. Obayashi.

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[2] At this juncture, the Court notes the parties have used a variety of terms to describe the absence of the 46 custodial files at issue. The PSC argues the files in question have been "destroyed," "deleted," or "otherwise lost," while Takeda has used various phrasing concerning the location of the documents, arguing the files have "not been located" or are, in some cases (particularly in the case of the "backup tapes"), "inaccessible." For purposes of spoliation, this Court finds Takeda has admitted it deleted or cannot produce the information contained within the 46 custodial files at issue, and once deleted, the information has been unable to be recovered or otherwise produced for the purposes of this litigation. Consequently, the Court concludes that regardless of the language used to describe the conduct of Takeda, it is clear Takeda deleted and cannot now produce relevant evidence, all as more fully set forth in this Memorandum Ruling.

[3] The following information concerning individuals whose custodial files are unavailable is extracted from Defendants' Exhibit 1, attached to the Opposition brief.

2. Kiyoshi Kitazawa, Managing Director, Board Member, and General Manager, Strategic Product Planning Department, who worked for TPC from April 1, 1971 to June 25, 2009. Takeda confirmed Mr. Kitazawa's e-mail account was deleted from active servers on October 1, 2009 and his personal file share and all personal data was deleted by a Takeda IT vendor on January 28, 2010 pursuant to a request dated January 20, 2010. Mr. Kitazawa's business documents were "discarded" at the time of his departure.

Argued to be contained within Dr. Kitazawa's custodial file(s) is correspondence uncovered through third-party discovery to Upjohn, a pharmaceutical company with whom Takeda sought to partner regarding the clinical development of Actos. In September 1993, Dr. J.B. Mitchell, the president of Upjohn, wrote to Dr. Tai Matsuzawa, a Vice President of the Takeda Pharmaceutical Group at Takeda Chemical Industries, Ltd. (another Japanese Takeda entity), as follows:

> On September 20 our Pharmaceutical Executive Council, **Upjohn's highest scientific decision-making body**, carefully reviewed the results of the **toxicology and clinical studies**. The decision of the Council was that **Upjohn will not go forward with pioglitazone** in the clinic. ***The Council decided that further clinical development of pioglitazone could not be justified based on their concern regarding pioglitazone's margin of safety.***[4]

In response, Dr. Kitazawa wrote to Dr. Patricia Ruppel, the Project Manager Director for Upjohn, suggesting revision of "Upjohn's statement," as follows:

> Regarding Upjohn's statement for the development status of pioglitazone, **we would like to propose the following alternative or a similar [sic] instead of Upjohn's proposal** in due consideration of our current development status.

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[4] *See* Letter from J.B. Mitchell to Tai Matsuzawa, dated September 21, 1993, attached as Exhibit 22 to the instant motion (emphasis added).

> In the very preliminary evaluation in the U.S.A., ***pioglitazone did not show the reduction of blood glucose enough to satisfy Upjohn's in-house requirement***. Any considerable work that would be needed is not in line with our business needs for further development of Pioglitazone. **Hence, all development on pioglitazone at Upjohn has ceased.**[5]

The PSC argues the foregoing discovery – found through third-party discovery rather than directly through production from Takeda – evidences bad faith on the part of Takeda by attempting to conceal Dr. Kitazawa's, and thus, Takeda's, conduct with Upjohn as to Actos.

3. Takashi Nonoyama, Associate Director, Pharmaceutical Research Division, Research Management Department, Planning & Development, who worked for TPC from April 1, 1971 to April 1, 2005. Mr. Nonoyama's e-mail account, personal file share, and personal computer were erased and no documents were found.[6]

4. Katsuhisa Saito, Senior Director, Pharmaceutical Development Division, Strategic Development Department, who worked for TPC from March 11, 1966 to April 1, 2004. Mr. Saito's e-mail account,[7] personal file share,[8] and personal computer were erased, and no documents were found. Additionally, no paper documents were found attributable to Mr. Saito.

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[5] *See* Letter from K. Kitazawa of Takeda to Patricia L. Ruppel, Director of Project Management at Upjohn, dated October 25, 1993, attached as Exhibit 23 to the instant motion (emphasis added).

[6] Mr. Nonoyama's successor, Mr. Masaki Yamamoto, remembers receiving some hard copy documents, and Mr. Yamamoto's documents relevant to Actos have been produced, therefore it is possible some of Mr. Nonoyama's documents might have been produced. However, it is known the entirety of Mr. Nonoyama's custodial file cannot be located and has not been produced. *See* Exhibit 10 to the instant motion.

[7] Takeda acknowledges 4,279 e-mails that were to/from/cc/bcc Mr. Saito have been produced. *See* Exhibit 10 to the instant motion.

[8] Takeda clarifies at the time of Mr. Saito's retirement, TPC did not have a company-wide server. Rather, each division/department managed its own servers. *Id.*

5. Kunio Takeda, Representative Director, Chairman of the Board, who worked for TPC from April 1, 1962 to June 25, 2009. Mr. Takeda's e-mail account[9] was deleted from active servers on October 1, 2009, and his personal file share was deleted from active servers on January 28, 2010.[10] Mr. Takeda's personal computer data was deleted at his request at the time of his separation from employment. Mr. Takeda's paper documents were also disposed of at the time of his departure.

6. Masaomi Miyamoto, Vice President, Pharmaceutical Research Division, who worked for TPC from April 1, 1975 to March 9, 2010. Mr. Miyamoto's e-mail account was deleted from active servers on July 2, 2010. Mr. Miyamoto's personal file share contained limited data, which was collected. Mr. Miyamoto used three (3) personal computers, however, none of which contained any data associated with Mr. Miyamoto. Takeda affirmed it was unable to locate any paper documents associated with Mr. Miyamoto.

7. Masahiro Miyazaki, Associate Director, Pharmaceutical Research Division, Strategic Research Planning Department,[11] who worked for TPC from April 1, 1984 to April 1, 2011. Mr. Miyazaki's e-mail account was deleted on July 1, 2011. Mr. Miyazaki's personal file share was located but did not contain any relevant Actos data. Mr. Miyazaki's personal computer data, however, was deleted on March 22, 2011. No paper documents have been located for Mr. Miyazaki.

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[9] Takeda has produced 227 e-mails that were to/from/cc/bcc Mr Takeda. *See* Exhibit 10 to the instant motion.

[10] This occurred when Takeda's IT deleted all personal file shares with no data. *Id.*

[11] Although Takeda identifies Mr. Miyazaki's role as an "Associate Director, Pharmaceutical Research Division, Strategic Research Planning Department," the PSC identifies Mr. Miyazaki's role as a "Senior Manager, Department of Strategic Development Pharmaceutical Development Division," perhaps reflecting the evolving nature of the hierarchy of the Japanese Takeda entities.

The following custodian files of *American Takeda* employees are also missing:

8. Harry (Dean) Hart,[12] Senior Vice President of Sales for Takeda Pharmaceuticals U.S.A., Inc. (formerly Takeda Pharmaceutical North America Inc.) ("TPUSA"). Mr. Hart worked for Takeda from January 17, 2000 to February 10, 2006. Mr. Hart's actual e-mail,[13] personal share file, personal computer data, and all paper files are unavailable.

9. Doug Joseph, Senior Manager of Product Safety at a Takeda entity named Takeda Development Center Americas, Inc. (f/k/a Takeda Global Research & Development Center, Inc.). Mr. Joseph was employed from November 30, 1999 to January 14, 2005. Mr. Joseph's actual e-mail,[14] personal share file, personal computer data, and all paper files are unavailable.

10. John Yates, President at Takeda Global Research & Development Center Inc. ("TGRD"). Mr. Yates was employed from January 1, 2004 to January 17, 2007. Mr. Yates' actual e-mail,[15] personal share file, personal computer data, and al paper or removable media files are unavailable.

The following custodial files are missing in *Europe*:

11. Phillip Collett, Vice President of Regulatory Affairs at Takeda Global Research and Development Centre (Europe) Ltd. Mr. Collett was employed from August 1998 through August 21, 2008. Mr. Collett's actual e-mail,[16] personal share file, and personal computer data

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[12] Takeda argues Mr. Hart's custodial file was never requested by the "MDL Plaintiffs." *See* Takeda's opposition brief, Doc. 3530, at p.1, n.2.

[13] Takeda has produced 7,102 e-mails that were to/from/cc/bcc Mr. Hart. *See* Exhibit 10 to the instant motion.

[14] Takeda has produced 4,613 e-mails that were to/from/cc/bcc Mr. Joseph. *Id.*

[15] Takeda has produced 13,469 e-mails that were to/from/cc/bcc Mr. Yates. *Id.*

[16] Takeda has produced 15,102 e-mails that were to/from/cc/bcc Mr. Collett. *Id.*

are unavailable. Takeda has located paper or removable media files for Mr. Collett, but is only now reviewing this evidence.

12. Annette Beiderbeck, Director of Epidemiology, Pharmacovigilance at Takeda Global Research and Development Centre (Europe) Ltd. Ms. Beiderbeck was employed from November 1, 2007 to January 16, 2010. Ms. Beiderbeck's actual e-mail,[17] personal share file, personal computer data, and all paper files are unavailable.

13. David Eckland, Managing Director at Takeda Europe Research & Development Centre. Ltd. Mr. Eckland was employed from October 28, 1998 to April 29, 2005. Mr. Eckland's actual e-mail,[18] personal share file, and personal computer date are unavailable. Takeda has, however, located paper or removable media files for Mr. Eckland, but is only now reviewing this evidence.

In addition to the employees listed above, Takeda, also, has failed to produce the custodial files of approximately twenty (20) sales representative. For these purposes, the Court will not describe the individual missing sales representative files with the same detail as those of the Takeda company president and clinical officers, as such individual distinctions is not required for this ruling, but notes the absence of those files and the relevant roles of sale representatives in marketing Actos.

B. Facts Relating to the Takeda Litigation Hold

The fact that certain evidence clearly has been deleted or destroyed does not end the inquiry, however. A party should be sanctioned only for destroying evidence *it had a duty to preserve*, and that duty "arises when the party has notice that the evidence is relevant to litigation

[17] Takeda has produced 5,254 e-mails that were to/from/cc/bcc Ms. Beiderbeck. *Id.*

[18] Takeda has produced 4,290 e-mails that were to/from/cc/bcc Mr. Eckland. *Id.*

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or when a party should have known that the evidence may be relevant to future litigation." *Zubulake v. UBS Warburg LLC*, 220 F.R.D. 212, 216 (S.D.N.Y. 2003) ("*Zubulake IV*"). Once a party reasonably anticipates litigation, it must suspend its routine document retention/destruction policy and put in place a "litigation hold" to ensure the preservation of relevant documents. *Zubulake IV*, 220 F.R.D. at 218. The issue of the precise date on which Takeda initiated a litigation hold for the preservation of documents related Actos litigation is hotly contested in this matter.

The Special Master and Deputy Special Master were managing discovery on behalf of the Court and, during a telephone conference among counsel conducted on May 28, 2013, instructed Takeda to provide the applicable litigation hold date to the PSC and Special Masters no later than June 6, 2013. On June 6, 2013, within the context of this MDL litigation, Takeda sent an e-mail to the Special Masters and PSC counsel advising them of the following:

> Finally, our understanding is that **Takeda issued its litigation hold notice for bladder cancer product liability litigation on February 15, 2011**. The inquiry of Takeda's counsel into these matters continue and written supplemental information will be provided.[19] (emphasis added)

The June 6, 2013 e-mail, also, noted that all of the Takeda employees for whom the PSC sought discoverable information had left Takeda's employment between February 2001 and April 2011. Further, Takeda claimed that all of the employees for whom files were requested had left their employment with Takeda *prior to the litigation hold date*, that it was then claiming was applicable, except for one employee – Mashahiro Miyazaki. According to Takeda, Mr. Miyazaki's *actual* departure date was April 1, 2011, but deletion of data from his PC occurred on

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[19] *See* e-mail dated June 6, 2013, attached as Exhibit 3 to the instant motion (emphasis added).

March 22, 2011, i.e., *prior to* his formal separation from employment, but *after* the claimed litigation hold date of February 15, 2011.

As promised in the June 6 e-mail, Takeda submitted supplemental information by e-mail dated June 14, 2013:

> Our understanding is that TPC issued a litigation hold notice for bladder cancer product liability litigation on September 2, 2011.[20]

This supplemental e-mail did not address the February 15, 2011 litigation hold date that had been provided by Takeda on June 6; rather, simply offered a *new date*, with no mention of the February 15, 2011 date which had been provided only eight days earlier.

C. Proceedings before the Magistrate Judge[21]

Much of what we now know about the missing documents came to light in proceedings before Magistrate Judge Hanna within the context of a discovery dispute concerning the issues raised in the instant motion. After Takeda ultimately admitted certain custodial files relevant to the instant litigation were "lost," "destroyed," or could not be produced, the PSC sought to conduct discovery to determine the extent to which documents were destroyed, and the circumstances surrounding that destruction (what, when, and why). Pursuant to that discovery, the PSC noticed Takeda's Rule 30(b)(6) deposition.[22] Takeda objected to the notice and filed a "Motion for Protective Order" [Doc. 2881] on June 18, 2013 seeking to limit the scope of discovery, necessitating the involvement of the Court, more specifically, primarily Magistrate

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[20] *See* e-mail dated June 14, 2013, attached as Exhibit 4 to the instant motion (emphasis added).

[21] Although the proceedings before the magistrate judge are primarily relevant to the PSC's request for sanctions pursuant to Rule 37, these proceedings, nevertheless, bear certain relevance to the issue of the Court's exercise of its inherent power to sanction a party for spoliation of evidence committed in sufficient bad faith.

[22] *See* "Notice of Oral and Video Deposition of [Takeda] Pursuant to Fed.R.Civ.P 30(b)(6)," attached as Exhibit A to Takeda's Motion for Protective Order, Doc. 2881.

Judge Hanna. Specifically, Takeda requested that if the Court allowed discovery, such discovery should be limited to written interrogatories only.

Contemporaneously with Takeda's filing, the PSC filed a Motion to Compel the Fed.R.Civ.P. 30(b)(6) Deposition on Takeda [Doc. 2884]; both motions were opposed [Docs. 2942, 2943]. On July 3, 2013, the magistrate judge conducted oral argument on both motions and concluded the PSC had presented *prima facie* evidence of "lost" or "destroyed" documents [*See* "Ruling on Motion," Doc. 2992]. *In his findings, the magistrate judge, also, noted Takeda had provided the PSC with inconsistent litigation hold dates.*[23] The magistrate judge granted plaintiffs' request for a 30(b)(6) deposition of Takeda, but divided the 30(b)(6) deposition into two phases: the first phase would be directed toward answering the question of whether or not the unproduced documents were, in fact, destroyed or otherwise unavailable to the PSC, while the second phase would be addressed to the issuance of a litigation hold, its enforcement, etc., and would proceed only if the Court determined that such document destruction had occurred in the first instance.[24] Magistrate Judge Hanna then ordered that a Takeda representative be prepared to testify: (a) regarding Topics 1 through 8 in the deposition notice; (b) on the topic of the routine, good-faith operation of an electronic information system as it pertains to the destruction of the files at issue; and (c) on the retrieval and/or reconstruction of the lost or destroyed documents by itself or a third party.[25] The magistrate judge deferred all other aspects of the Motion to Compel until after completion of the first phase of the 30(b)(6) deposition. As to Takeda's Motion for Protective Order, the magistrate judge limited the historical time period for inquiry into noticed topics to the time period beginning January 1, 2010 - just before the first declared February 15, 2011 hold date;[26] denied the request to conduct discovery through written interrogatories; and deferred additional ruling pending the completion of the 30(b)(6) deposition.

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[23] *See* "Ruling on Motion," Doc. 2992, at pp 6-7.

[24] See "Ruling on Motion," Doc. 2992, at p. 8.

[25] *See* "Ruling on Motion," Doc. 2992, at p. 9.

On July 25, 2013, before the scheduled first phase of the 30(b)(6) deposition, at the request of the parties, the magistrate judge heard additional argument for the purpose of clarifying certain aspects of his ruling. At that hearing, upon question by the Court, the PSC argues *Takeda's counsel, for the first time, advised the Court that claims, settlements, and litigation involving Actos product liability went back as far as 2002.*[27] Shortly thereafter, by written discovery responses, Takeda acknowledged for the first time that it had instituted a "***general*** Actos® 'products liability' litigation hold" in July 2002 (the "2002 Litigation Hold"), and provided a schedule of Actos-related personal injury claims and litigation.[28] The **2002 Litigation Hold**, issued in the United States on July 19, 2001 reads:

> A motion has been filed to add Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. as defendants in a lawsuit. **The plaintiff in this lawsuit** seeks **damages for personal injury and wrongful death allegedly resulting from the use of** certain prescription drugs, including **Actos**.
>
> To be able to respond to discovery requests from the plaintiff, if that becomes necessary, we must take steps to preserve any documents that may be called for in this lawsuit.
>
> ***Until further notice, you are instructed to preserve any and all documents and electronic data which discuss, mention, or relate to Actos. This means do not destroy, delete, throw away or otherwise discard any such documents or***

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[26] *See* Transcript of Motion Hearing by Telephone, Doc. 2977, at p.28. This date was chosen by the Court because it was the earliest date Magistrate Judge Hanna believed - based upon representations made to the Court during oral argument - the issuance of a litigation hold could have occurred in this matter.

[27] *See* Transcript of Hearing, Doc. 3091, at p. 51:25-54:4.

[28] *See* "Takeda's Response and Objections to Plaintiffs' Supplemental Interrogatory 2," attached as Exhibit 15 to Plaintiffs' Memorandum, and "Attachment A to Takeda's Response to Plaintiffs' Supplemental Interrogatory No. 2," attached as Exhibit 6 to Memorandum.

electronic data. This includes correspondence, records, and data, contained in your paper and electronic files, regardless of form and including email correspondence and attachments and electronic data.

Action Steps:

Please interpret this directive in its broadest sense to prevent the deletion or destruction of any recorded information and data relating in any way to Actos.

Please take steps immediately to preserve such documents and data within your department.

Please distribute this memo to members of your group and advise them of the importance of following these instructions.[29]

This 2002 general Actos products liability hold was "refreshed" several times over the relevant time period, September 17, 2003, May 4, 2006, October 22, 2007, January 14, 2008, and February 15, 2011.[30]

Once the existence of the foregoing information was revealed and had been placed into the record, the magistrate judge amended his discovery ruling to include, among other things, a revised beginning date for the PSC's discovery inquiries - January 1, 2002.[31]

D. The 30(b)(6) Deposition of Takeda

Consequently, the deposition of Takeda pursuant to Fed. R. Civ. P. 30(b)(6) was scheduled in light of Magistrate Judge Hanna's rulings. Takeda chose to designate as its selected representative at this deposition, an "IT consultant," who had no independent personal or corporate knowledge of any of the Takeda entities or policies and who had never worked with or for, in any capacity,[32] any of the Takeda entities prior to his being hired for the specific purpose of acting as the Takeda corporate representative designated as an "other person who consent[s] to testify on its behalf."[33] The PSC argues the 30(b)(6) designation and nature of the resultant deposition of Takeda demonstrates, itself, bad faith on the part of Takeda within the discovery process, and a limited discussion of this argument is, therefore, appropriate at this juncture.[34]

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[29] *See* 2002 Litigation Hold, attached as Exhibit 13 to the instant motion. (certain emphasis in original; certain emphasis added)

[30] *See* "Declaration of Stacey Dixon Calahan," attached as Exhibit 3 to Takeda's opposition brief, Doc. 3530, at ¶13.

[31] *See* Amended Order, Rec. Doc. 3056, at p.2.

The 30(b)(6) deposition of Takeda was conducted over a period of four days, on August 19-20, 2013 and on September 18-19, 2013. Only one witness was presented and that witness *had no personal or first hand corporate knowledge of any kind* of any of the topics about which he was questioned. Rather, the PSC argues he was, in effect, merely a hired gun brought in by Takeda to provide a buffer and to obfuscate on Takeda's behalf - and this Court, after review of the 30(b)(6) deposition, cannot say the deposition does not support that argument. After the August 19 and 20 sessions, the magistrate judge, again, issued yet another Amended Order requiring Takeda *to further respond,* now to nine (9) specific topics of inquiry, and ordering supplemental briefing on selected issues[35] - matters the 30(b)(6) representative either did not or

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[32] In his deposition, Mr. Regard stated that he worked on a project for Takeda back in 2010, wherein he was asked to do some analysis and testimony regarding, he believes, a patent dispute. Deposition of Daniel Regard attached as Exhibit 8, to the instant motion [Doc. 3484-2] at p. 32.

[33] Fed.R.Civ.P. 30(b)(6).

[34] Whether Takeda's conduct as to the 30(b)(6) constitutes a violation of Fed. R. Civ. P. 30(b)(6) is a matter this Court will give close attention when addressing Fed. R. Civ. P. 37 and the alleged violations - a matter this Court, at this time, reserves for later consideration. However, whether *the nature of the selection* and information produced and testified to might, also, be evidence of bad faith on the part of Takeda as to spoliation, is relevant to the inquiry at hand.

[35] The nine topics for inquiry were:

- The name of the entity (or entities) which employed each of the 36 custodians identified in Mr. Saylor's August 15, 2013 correspondence to Mr. Bassett;

could not address, notwithstanding his having been selected by Takeda as their corporate representative pursuant to Takeda's obligation under the Federal Rules of Civil Procedure.

Takeda had designated Daniel L. Regard, II, *an electronic discovery consultant* who *did not and does not work for any Takeda entity*, other than as a consultant, but rather, was retained, it would seem, solely for the purpose(s) of this litigation and to act as Takeda's 30(b)(6) designee. In preparation for the deposition, Mr. Regard - again, who had no personal or first hand corporate knowledge of any kind of any Takeda entity- testified he conducted dozens of employee interviews, went on site visits, and reviewed numerous Takeda documents and policies in preparation for the deposition. However, it is clear from a review of the interviews he conducted that Mr. Regard spoke only to certain and select Takeda employees about certain and select issues related to the subject matter designated for the 30(b)(6) deposition. For example, it

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- The positions held by each of the foregoing custodians throughout their employment histories;
- The date of hire and the last date of employment for each custodian;
- The identity of any and all "successors" to the custodians as described in the 30(b)(6) depositions and whether the successors' custodial files have been produced;
- The degree to which Takeda contends materials that "would have been" in the custodians' files – which have not been located– either have already been produced to the PSC by other means (i.e. through "corporate records" or "successors" custodial files) or have been withheld as privileged;
- A **true** estimate of the **total** cost of retrieval/reconstruction of custodial files that have not been located for the custodians in the United States from the 2002 Litigation Hold to present day under any of the options presented in the testimony;
- A **true** estimate of the total cost of retrieving/reconstructing the EU custodians' files, unless it is accurate that there are no longer any missing EU custodial files;
- A **true** estimate of the **total** costs of retrieving/reconstructing the Japanese custodians' files, i.e. through metadata searches by sender, or a declaration that retrieval is simply not possible. Takeda is cautioned that incomplete or evasive answers to this Court's inquiry will be viewed as a failure to answer pursuant to Fed. R. Civ. P. 37(a)(4);
- Whether any effort has been made to reconstruct the missing custodial files, and if so, the result of that effort.

is not at all clear that Mr. Regard spoke to many information technology ("IT") employees at Takeda, and, his deposition reflects, he did not have a strong grasp of Takeda's actual IT procedures and their interplay with litigation hold policies and procedures, generally, or as among the various Takeda entities. Furthermore, for example, although a listing provided identifying individuals Mr. Regard interviewed reflects he interviewed Stacey Calahan, Assistant General Litigation Counsel for Takeda Pharmaceuticals USA, Inc., it does not appear Mr. Regard discussed with her the evolution of Takeda's document retention policies *vis-à-vis* the specific litigation holds at issue in this litigation.[36] This Court notes this fact only because Takeda submitted a thirteen (13) page document, which was filed October 30, 2013, after the deposition of Mr. Regard, entitled "Declaration of Stacey Dixon Calahan" - which will be discussed in further detail below - in opposition to the PSC's motion on that very topic. It is wholly undisputed Mr. Regard had no personal knowledge of any of the corporate history, conduct, or internal workings of any Takeda entity, as he has never worked for Takeda other than as a consultant, other than to be retained for the purposes of representing Takeda at the 30(b)(6) deposition.

Mr. Regard's testimony concerning Takeda's document retention policies, and specifically, the use of "backup tapes" to retain information related to litigation, is specifically

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36 Q: Okay. So why – when you talked to Ms. Calahan, when she said she was – this was just some sort of refresh unrelated to any bladder cancer or any particular event, why did she completely redraft the hold?

A: I did not ask her that question.

Q: Why not? Why didn't you ask her that?

A: It didn't occur to me at the time to ask her.

See Deposition of Daniel Regard, at pp. 782-783.

argued by the PSC as evidence of Takeda's bad faith. At the deposition, PSC counsel questioned Mr. Regard about the existence of Takeda "Business Operating Procedure-019 (Corp-B019),"[37] which contains a section entitled "E-mail Management and Retention," which states the following:

> 1.0 Purpose
>
> The purpose of this Operating Procedure is to describe the requirements for personnel of Takeda Pharmaceuticals North America, Inc., Takeda Global Research and Development Center, Inc. and their U.S. subsidiaries (*collectively Takeda*) ***to fulfill our legal, financial, regulatory, and organizational obligations as they relate to Email Management and Retention***.

Corp-B019 also contains a section entitled " Restrictions on Use of Disaster Recovery Back-up Tapes," which states:

> 5.10 Restrictions on Use of Disaster Recovery Back-up Tapes:
>
> ***Following implementation of this Operating Procedure disaster recovery backup tapes and disks that are used for business continuity or disaster purposes shall not be used for any other purpose, and shall not to [sic] be used to satisfy retention requirements for Company E-mail records or Legal Hold materials.***

The foregoing retention policy had an effective date of May 1, 2006.

PSC counsel questioned Mr. Regard about the existence of the foregoing policy, as follows:

> Q: So this is B-019, and this is one where you said, you know, we – there's some sort of debate, I guess, as to whether this is in effect or a best practice. But either way, whether it's a policy or standard operating procedure or best practice, does it not clearly state that you are not to use your backup systems to satisfy the requirements for retaining email; records or legal hold materials?
>
> A: No, sir, it does not state that.

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[37] *See* Corp-B019, attached as Exhibit 17 to the instant motion.

Q: All right. Explain that to me.

A: The company makes many different types of backup tapes on a regular basis. The company makes short-term operational tapes and disaster recovery tapes that are recycled. The company makes in the U.S. a bi-weekly set of backup tapes for retention purposes. The company does not consider retention tapes to be the disaster recovery tapes. That's a separate set of tapes that are recycled regularly and not relied upon for litigation hold purposes.

Q: Has [sic] the tapes that you described, the first tapes, are they more accessible than the second tapes?

A: Are the disaster recovery tapes more accessible than the litigation hold tapes?

Q: Yes.

A: I don't know which –

Q: Either way.

A: The disaster recovery tapes are created and recycled on a short-term cycle.

[. . .]

Q: So here is a – is there – is there a procedure that says you can use – you can't use disaster recovery backup tapes, but the other types of backup tapes that you're describing, is there some written procedure that says that you can use those tapes for legal hold purposes?

A: **I haven't seen a written procedure. The fact of the matter is the company has created these tapes as part of the litigation hold exercise.**

. . .

Q: . . . Why isn't – if that's an important part of your responsibility with complying with litigation hold procedures, why would that – why would everything else, every other policy that deals with litigation holds be written and that not be in writing?

MR. SAYLER: Objection; misstates the facts.

[. . . .]

A: **I don't think** the backup tapes are part of the responsibility of the company, but the backup tapes form a part of the company's response to

> what it feels its responsibility is. I just want to – I don't want to get mixed up on words. The company started saving bi-weekly litiga - retention backup tapes is how they refer to them as – **after the July 2002 claim was filed.**[38]

Mr. Regard, however, went on to testify Corp-B019 was never fully implemented,[39] and yet, when asked whether Takeda's new employee training manual references Corp-B019 as a "Policy and Procedure" to follow for guidance on records management and compliance, Mr. Regard acknowledged new employees were indeed trained on the policies contained within Corp-B019. Additionally, counsel for Takeda, in response to certain written discovery propounded by the PSC, confirmed the existence of a 2006 Takeda published document titled "BEST PRACTICES FOR THE PHYSICAL AND ELECTRONIC STORAGE OF MATERIALS THAT MUST BE RETAINED FOR LEGAL REASONS INDEPENDENT OF CORPORATE RETENTION GUIDELINES or 'LEGAL HOLDS'" ("Best Practices Document"), which states:

> **To effectuate this Policy, the Outlook system has been configured to ensure that responsive materials that are accidentally deleted cannot be lost. Such materials, even to the extent that you empty your deleted items, will be captured in the bi-weekly back-up tape. *HOWEVER, BECAUSE OF THE EXPENSE OF SEARCHING BACK-UP MEDIA FOR LEGAL HOLD OR RESPONSIVE MATERIALS, TAKEDA MANAGEMENT HAS MADE THE STORAGE OF SUCH MATERIALS WITHIN OUTLOOK BY EMPLOYEES AND CONTRACTORS MANDATORY. THEREFORE, RESPONSIVE MATERIALS SHALL NOT BE DELETED.***[40]

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[38] *See* Deposition of Daniel L. Regard, II, attached as Exhibit 8 to the instant motion, at pp. 726-29. (emphasis added)

[39] *See Id.* at pp. 130-134.

[40] *See* "Best Practices Document," attached as Exhibit 18 to the instant motion.

See also "Takeda's Verified Response to Plaintiffs' Discovery Requests served September 23, 2013, as Amended September 24, 2013, with Question 1A" attached as Exhibit 14 to the instant motion, at p. 3, as follows.

1A a. On what date did TGRD EU or any of the European Takeda entities first

The 2006 document contains the following additional instruction on multiple pages of the document: "You are reminded that you must follow the requirements of both BOP, CORP-B-019 'Email Management and Retention' for the retention of electronic materials," thereby instructing recipients of the 2006 Litigation Hold that they must follow Corp-B019.[41]

Additionally, the 2006 Legal Hold instructs:

> For electronic information, documents, and materials in Takeda's electronic information management systems, including electronic materials saved in your desktop computer, **you are reminded that this material may NOT be deleted under any circumstances** (emphasis original).[42]

However, since May 22, 2013, within this MDL litigation, Takeda has argued it should **not** be required to produce information from backup tapes, as such tapes are normally considered "inaccessible." Alternatively, Takeda has argued that if this Court were to conclude the information on its backup tapes were to be determined to be "accessible," and, therefore, discoverable, the Court should entertain a cost-shifting analysis requiring the PSC to share some

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> become aware of the July 19, 2002 legal hold?
>
> ANSWER: Takeda does not have a specific date when TGRD Europe (now known as Takeda Development Centre Europe, Ltd.) or the European Takeda Entities first became aware. **TGRD Europe had access to the July 19, 2002 legal hold,** in **the form of the 2006 refresh notice**, when the 2006 refresh notice was posted to Takeda's Horizon intranet site in April or May 2006. To the best of Takeda's knowledge and belief, no other European Takeda entity was aware of the July 19, 2002 legal hold before then. (emphasis added)

The PSC has suggested the February 2010 "refresh" of the 2002 Litigation Hold was implemented after, and because of, the September 2010 bladder cancer "claim" (not a lawsuit), however, it is evident from Mr. Regard's testimony that Takeda has attempted to distance itself from this notion, suggesting the February 2011 "refresh" was implemented "because it had been so long since a refresh had been issued." *See* Deposition of Mr. Regard, at pp. 680-81.

[41] *See* 2006 Litigation Hold, attached as Exhibit 20 to the instant motion.

[42] *Id.*

of the financial burden associated with such production.[43] The apparent inconsistent interplay between the position taken by Takeda within the context of the ongoing discovery dispute and Mr. Regard's testimony is disconcerting, at best and the PSC argues is evidence of Takeda's culpable intent.

The foregoing are presented by way of examples, only, of the arguments made and evidence cited by the PSC as to the Regard deposition and are in no way to be considered either complete or exclusive.

E. Motion Before the Court

After the completion of the Takeda 30(b)(6) deposition, the PSC notified the Court, through the Special Masters, that they intended to file the instant motion and that, in view of the Court's ruling indicating that it intends to conduct its own inquiry into Takeda's Rule 37 conduct,[44] informed the Court that no further discovery would be required before the motion would be filed. The PSC argues violation of Fed.R.Civ.P. 37 and spoliation and requests various sanctions as to each and as to both.

III. Legal Standards

A. Power of the Court to Sanction

The Federal Rules of Civil Procedure govern alleged violations of Fed.R.Civ.P. 30(b)(6) and Fed.R.Civ.P. 37; spoliation of evidence in this instance, is an evidentiary question grounded within a discovery dispute, and in federal diversity cases, federal courts apply federal law to the issue of discovery abuse, rather than state law.[45] *Condrey v. SunTrust Bank of Georgia*, 431 F.3d 191, 203 (5th Cir. 2005), *citing King v. Illinois Cent. R. R.*, 337 F.3d 550, 556 (5th Cir. 2003). This Court has the authority to impose sanctions relating to spoliation of evidence, primarily, by way of two sources: (1) its inherent power to control the judicial process and litigation; and (2) Rule 37 of the Federal Rules of Civil Procedure.[46] Under Rule 37, a court may issue an order imposing an array of sanctions if a party "fails to obey an order to provide or permit discovery." Fed.R.Civ.P. 37(b)(2)(A). As spoliation more often grows out of discovery disputes, the majority of the jurisprudence on this issue is found within the district courts. District courts in the Fifth Circuit have generally held Rule 37 better applies to a party's misconduct *after litigation has commenced*, by way of example *see, e.g., Rimkus v. Consulting Group, Inc. v. Cammarata*, 688 F.Supp.2d 598, 612 (S.D. Tex. 2010) (J. Rosenthal). Furthermore, the Fifth Circuit has held sanctions under Rule 37 are typically limited *to specific* discovery violations, "serving foremost to penalize misconduct, *especially when levied against an attorney personally*." *Sample v. Miles*, 239 Fed.Appx. 14, 20 n.14 (5th Cir. 2007) (unpublished), *citing Coane v. Ferrara Pan Candy Co.*, 898 F.2d 1030, 1033 n. 2 (5th Cir. 1990) (emphasis added). Importantly, Rule 37 does not require a showing of "bad faith," and the Fifth Circuit has found "[t]he bandwidth of the District Court's power to impose Rule 37 sanctions is broad indeed." *Marshall v. Segona*, 621 F.2d 763, 766 (5th Cir. 1980).

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[43] *See* "Takeda Defendants' Legal Position in Opposition to Discovery from Backup Tapes for Former Employees of Takeda Pharmaceutical Company, Ltd." attached as Exhibit 16 to the instant motion, at pp 4-5. The Court notes Takeda has never formally requested a ruling that their backup files are actually "discoverable." Nevertheless, in response to the PSC's instant motion, Takeda asks this Court to engage in a cost-shifting analysis to require the PSC to bear some of the costs associated with the production of information contained on Takeda's "backup files."

[44] *See* Supplemental Ruling on Motions, attached as Plaintiffs' Exhibit 1, at 11. In this Ruling, the magistrate judge noted that discovery into the issue of spoliation would be addressed by the Court, and not counsel. Based on the foregoing, the PSC notified the Special Masters it would be conducting no additional discovery at that time.

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[45] The PSC had previously reserved their right to allege an independent *cause of action* under state law for spoliation. However, this Court notes no argument has been made by the PSC that a state cause of action exists, nor has the PSC requested relief under a state cause of action. Therefore, the Court will proceed with its analysis of the instant motion as an evidentiary issue inherent in and growing out of discovery, which is governed by federal law. This Court also considers any claim in this matter of an independent tort for spoliation to be waived, as this Court ordered that the briefing on spoliation to contain all points and all legal arguments under which relief was sought. Consequently, any claim based upon an independent spoliation tort or open question on choice of law is deemed waived as to the Allen case, only.

[46] Rule 37(b)(2)(A) states:

(b) Failure to Comply with a Court Order.

(2) Sanctions Sought in the District Where the Action Is Pending.

(A) For Not Obeying a Discovery Order. If a party or a party's officer, director, or managing agent--or a witness designated under Rule 30(b)(6) or 31(a)(4)--fails to obey an order to provide or permit discovery, including an order under Rule 26(f), 35, or 37(a), the court where the action is pending may issue further just orders. They may include the following:

(i) directing that the matters embraced in the order or other designated facts be taken as established for purposes of the action, as the prevailing party claims;

(ii) prohibiting the disobedient party from supporting or opposing designated claims or defenses, or from introducing designated matters in evidence;

(iii) striking pleadings in whole or in part;

(iv) staying further proceedings until the order is obeyed;

(v) dismissing the action or proceeding in whole or in part;

(vi) rendering a default judgment against the disobedient party; or

(vii) treating as contempt of court the failure to obey any order except an order to submit to a physical or mental examination.

On the other hand, conduct that occurs *prior to* the commencement of litigation has more often been addressed by the district courts through the Court's inherent powers. A federal court's inherent authority is invoked where there is no statute or rule that adequately addresses the conduct. *Sample*, 239 Fed.Appx. at 20 n.14, *citing Coane v. Ferrara Pan Candy Co.*, 898 F.2d 1030, 1033 n. 2 (5th Cir. 1990). However, in *Chambers v. NASCO, Inc.*, the United States Supreme Court counseled caution when a court proceeds to impose sanctions under its inherent power, as follows:

There is, therefore, nothing in the other sanctioning mechanisms or prior cases

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Fed.R.Civ.P. 37(b)(2)(A).

> interpreting them that warrants a conclusion that a federal court may not, as a matter of law, resort to its inherent power to impose attorney's fees as a sanction for bad-faith conduct. This is plainly the case where the conduct at issue is not covered by one of the other sanctioning provisions. **But neither is a federal court forbidden to sanction bad-faith conduct by means of the inherent power simply because that conduct could also be sanctioned under the statute or the Rules.** ***A court must, of course, exercise caution in invoking its inherent power, and it must comply with the mandates of due process, both in determining that the requisite bad faith exists and in assessing fees***. Furthermore, when there is bad-faith conduct in the course of litigation that could be adequately sanctioned under the Rules, the court ordinarily should rely on the Rules rather than the inherent power. **But if in the informed discretion of the court, neither the statute nor the Rules are up to the task, the court may safely rely on its inherent power.**

501 U.S. 32, 50, 111 S.Ct. 2123, 2135, 115 L.Ed.2d 27 (1991) (emphasis added) (internal citations omitted). The *Chambers* case makes clear where the court's inherent power provides the source of authority for sanctions, the conduct at issue must involve some degree of bad faith. *See also Sample*, *supra* at 20 n.14. Furthermore, as a general matter, a court should only impose a consequence that is "limited to that necessary to redress conduct 'which abuses the judicial process.'" *See Silvestri v. General Motors Corp.*, 271 F.3d 583, 590 (4th Cir. 2010), *citing Chambers*, 501 U.S. at 45-46 and the Fifth Circuit has stated:

> We upheld the inherent power of courts to issue sanctions beyond those available in sanctions rules in *NASCO v. Calcasieu Television & Radio*, which the Supreme Court subsequently affirmed in *Chambers*. In *Calcasieu*, we found that "federal courts enjoy a zone of implied power incident to their judicial duty," and that this inherent power is "'governed not by rule or statute but by the control necessarily vested in courts to manage their own affairs.'" ***However, like the power to sanction vested in courts by Rule 11, [t]o the extent that inherent power is seen as a product of necessity, it contains its own limits. It is not a broad reservoir of power, ready at an imperial hand, but a limited source; an implied power squeezed from the need to make the court function.***

FDIC v. Maxxam, Inc., 523 F.3d 566, 591 (5th Cir. 2008) (emphasis added) (internal citations omitted), *quoting NASCO, Inc. v. Calcasieu Television & Radio, Inc.*, 894 F.2d 696, 702-04 (5th Cir.1990), *aff'd sub nom., Chambers v. NASCO, Inc.*, 501 U.S. 32, 50, 111 S.Ct. 2123, 2135, 115

L.Ed.2d 27 (1991). The Fifth Circuit has further explained:

> The threshold for the use of the inherent power sanction is high. ***Such powers may be exercised only if essential to preserve the authority of the court and the sanction chosen must employ 'the least possible power adequate to the end proposed.'*** **If there is a reasonable probability that a lesser sanction will have the desired effect, the court must try the less restrictive measure first.**

Natural Gas Pipeline Co. Of America v. Energy Gathering, Inc., 86 F.3d 464 (5th Cir. 1996) (emphasis added), *citing Reed v. Iowa Marine & Repair Co.*, 16 F.3d 82 (5th Cir. 1994) and *Spallone v. United States*, 493 U.S. 265, 280, 110 S.Ct. 625, 635, 107 L.Ed.2d 644 (1990)(emphasis added). The PSC moves for sanctions under both this Court's inherent authority and Rule 37. In the instant case, because the alleged actual deletion of documents appears to have occurred *before* the official commencement of litigation and does not implicate involvement of any counsel now before the Court, this Court finds as to that conduct, the power to sanction would more clearly arise under its inherent powers. Nevertheless, to the extent actions taken by Takeda's counsel *after* the commencement of litigation are alleged by the PSC, Rule 37 would likely provide the Court's source of authority to impose sanctions.

Mindful of the United States Supreme Court's counsel of caution when imposing sanctions under its inherent powers, and considering the strenuous arguments advanced by Takeda that the evidence presented bears reasonable explanation and that it has engaged in good faith in crafting and executing its document retention policies and in participating in discovery in this matter, and the strenuous argument made by the PSC to the contrary as to each point, and as this Court finds a full appreciation of the importance of the evidence argued is needed in order to grant a complete context for an evaluation this Court will, for these limited purposes only, separate the request made under Rule 37 from that made under this Court's inherent powers, and this Court will DEFER the PSC's request for sanctions under Rule 37 until the close of evidence.[47] Consequently, in the instant Ruling, this Court will address only the PSC's request for spoliation sanctions under the Court's inherent authority to impose same.

B. Spoliation Law[48]

This Court notes the law of spoliation and sanctions contained therein is an area of the law that has grown out of certain general principles set forth in *The Sedona Principles: Best Practices, Recommendations & Principles for Addressing Electronic Document Discovery* (Sedona Conference Working Group Series 2003 and Second Edition 2007), and articulated within the *Zubulake* decisions from the Southern District of New York. As noted by Magistrate Judge Noland of the Middle District of Louisiana, as the Fifth Circuit has not directly addressed the standards for the preservation of electronic evidence and applicable sanctions where such evidence has been spoliated, this Court must look to other circuit courts, and to other district courts within the Fifth Circuit, as well as to persuasive authority from other jurisdictions, including the *Zubulake* decisions, for guidance. *Consolidated Aluminum Corp. v. Alcoa, Inc.*, 244 F.R.D. 335, 339 (M.D. La. 2006) (M.J. Noland). In *Rimkus, supra* at 613, Judge Lee Rosenthal, of the Southern District of Texas, cautioned against "a categorical approach to sanctions," calling the foregoing "difficult," and this Court agrees with my esteemed colleague. Consequently, this Court will proceed with caution when sailing into these uncharted and perhaps perilous waters, and will look to the experience of its sister courts for guidance. The cases most often cited for setting the benchmark standards for modern discovery and electronic evidence-preservation issues are the series of *Zubulake* decisions out of the Southern District of New York.[49] This Court will refer to this series of decisions as *Zubulake I-V*.[50] According to *Zubulake IV,* spoliation is defined as the "destruction or significant alteration of evidence, or the failure to preserve property for another's use as evidence in pending or reasonably foreseeable litigation." *Zubulake IV, supra* at 216, *citing West v. Goodyear Tire & Rubber Co.*, 167 F.3d 776, 779 (2nd Cir. 1999). Certain courts within the Fifth Circuit, also, have found "concealment of evidence" to constitute spoliation.[51] As *Zubulake IV* instructs, the spoliation of evidence germane to "proof of an issue at trial can support an inference that the evidence would have been unfavorable to the party responsible for its destruction." 220 F.R.D. at 216.

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[47] Consequently, in this Ruling, the Court makes no determination as to the conduct of Takeda's counsel, but rather addresses the conduct of Takeda. Thus, this Court expressly DEFERS evaluating whether sanctions are warranted against Takeda's counsel under Fed.R.Civ.P 37© as the PSC argues, until after this Court has had opportunity to fully explore that conduct and, also, notes that the majority of the argued conduct occurred within Magistrate Judge Hanna's Court and within the context of his orders. Consequently, this Court reserves its right to refer that matter to the magistrate judge, if deemed appropriate.

[48] *See* fn 45.

The mere destruction or alteration of evidence, however, does not, necessarily, mandate a finding that a party has engaged *in sanction-worthy* spoliation. *Ashton v. Knight Transp., Inc.*, 772 F.Supp.2d 772, 799-800 (N.D. Tex. 2011) (J. Boyle). Rather, a party should only be sanctioned for destroying evidence *it had a duty to preserve*, and that duty "arises when the party has notice that the evidence is relevant to litigation or when a party should have known that the evidence may be relevant to future litigation." *Zubulake IV*, 220 F.R.D. at 216. This Court agrees with *Zubulake IV,* however, that the foregoing duty does not require a corporation to

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49 Although the PSC alleges the loss or destruction of some paper documents, the bulk of the PSC's allegations concern(s) electronic evidence.

50 *Zubulake v. UBS Warburg, LLC*, 217 F.R.D. 309 (S.D.N.Y.2003) (J. Scheindlin); *Zubulake v. UBS Warburg, LLC*, 230 F.R.D. 290 (S.D.N.Y.2003) (J. Scheindlin); *Zubulake v. UBS Warburg, LLC*, 216 F.R.D. 280 (S.D.N.Y.2003) (J. Scheindlin); *Zubulake v. UBS Warburg, LLC*, 220 F.R.D. 212 (S.D.N.Y.2003) (J. Scheindlin); and *Zubulake v. UBS Warburg, LLC*, 229 F.R.D. 422 (S.D.N.Y.2004) (J. Scheindlin).

51 *See generally Toth v. Calcasieu Parish*, 06-998, 2009 WL 528245 at *1 (W.D.La. Mar 2, 2009) (J. Trimble).

preserve "every shred of paper, every e-mail or electronic document, and every backup tape." *Id.* at 217. Nonetheless, the duty does extend to "any documents or tangible things made by individuals 'likely to have discoverable information that the disclosing party may use to support its claims or defenses.'" *Id.* The duty to preserve has been summarized as follows:

> Once a party reasonably anticipates litigation, it *must suspend its routine document retention/destruction policy* and *put in place a "litigation hold"* to *ensure the preservation* of relevant documents. As a general rule, that litigation hold *does not apply to inaccessible backup tapes* (e.g., those typically maintained solely for the purpose of disaster recovery), which may continue to be recycled on the schedule set forth in the company's policy. On the other hand, *if backup tapes are accessible* (i.e., actively used for information retrieval), then such tapes would *likely be subject to the litigation hold.*

Id. at 218 (emphasis added).

This Court, also, agrees the preservation obligation should extend well beyond simply implementing a litigation hold. Indeed, once a litigation hold is in place, a party and its counsel must make certain all sources of potentially relevant information are identified and placed "on hold." *Id.* at 218. Without such affirmative action, a litigation hold would be mere empty verbiage.

Finally, this Court, also, agrees the determination of a proper sanction, if any, for spoliation is grounded within the sound discretion of the trial judge, and should be determined on a case-by-case basis. *Id.*

IV. Analysis and Discussion

A. Destruction of Evidence

Takeda admits it is unable to produce forty-six (46) custodial files of Takeda clinical employees and Takeda sales representatives.[52] It is undisputed thirty-eight of these custodial files were deleted from the active Takeda servers after 2002. It cannot seriously be questioned that, in fact, the missing files belonged to both high-ranking Takeda officials heavily involved in the development, sales, marketing and promotion of ACTOS, as well as rank-and file sales representatives whose day-to-day work involved marketing and distributing ACTOS in the marketplace. The titles of the employees whose files cannot be produced, themselves, evidence the potential importance and relevance of the missing information. In Japan alone, employees whose files cannot be produced include:

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[52] *See* "No-File Custodian Summary Sheets," attached as Exhibit 1 to Takeda's opposition brief, Doc. 3530.

1. Mikihiko "Ken" Obayashi (**Director, Pharmaceutical Development Division**);

2. Kiyoshi Kitazawa (**Managing Director, Board Member, and General Manager, Strategic Product Planning Department**)

3. Takashi Nonoyama (**Associate Director, Pharmaceutical Research Division, Research Management Department, Planning & Development**) (although some of Mr. Nonoyama's documents may have been produced because they are contained within the file of his successor);

4. Katsuhisa Saito (**Senior Director, Pharmaceutical Development Division, Strategic Development Department**); Kunio Takeda (**Representative Director, Chairman of the Board**); and

5. Masaomi Miyamoto (**Vice President, Pharmaceutical Research Division**).

The titles of the following American and European Takeda employees, also, demonstrate the potential relevance of these former employees' missing files:

6. Harry (Dean) Hart (**Senior Vice President of Sales for Takeda Pharmaceuticals U.S.A., Inc.** (formerly Takeda Pharmaceutical North America Inc.) ("TPUSA");

7. Doug Joseph (**Senior Manager of Product Safety at a Takeda entity named Takeda Development Center Americas, Inc.** (f/k/a Takeda Global Research & Development Center, Inc.);

8. John Yates (**President at Takeda Global Research & Development Center Inc.** ("TGRD");

9. Phillip Collett (**Vice President of Regulatory Affairs at Takeda Global**

Research and Development Centre (Europe) Ltd.);

10. Annette Beiderbeck (**Director of Epidemiology, Pharmacovigilance at Takeda Global Research and Development Centre (Europe) Ltd**.); and

11. David Eckland (**Managing Director at Takeda Europe Research & Development Centre. Ltd.**).

The breadth of Takeda leadership whose files have been lost, deleted or destroyed is, in and of itself, disturbing. It would appear from the record, one of the more troubling of these missing files is that of Masahiro Miyazaki, **Associate Director, Pharmaceutical Research Division, Strategic Research Planning Department**, who ***worked for TPC for approximately thirty years*** and whose experience within Takeda, at a variety of posts within the pharmaceutical division of Takeda Japan, suggests a wealth of knowledge and information concerning the development, marketing, and promotion of ACTOS which has forever been lost. Importantly, it appears Mr. Miyazaki separated from Takeda sometime in ***April 2011***, although it is unclear exactly when Mr. Miyazaki's employment *officially terminated*. Nevertheless, Takeda admits Mr. Miyazaki's e-mail account was deleted *on July 1, 2011*[53] and *his personal computer data* ***was deleted on March 22, 2011***.[54] Thus, Takeda admits it destroyed Mr. Miyazaki's personal computer data **before** he officially left the company. Considering Takeda has admitted, even as to *bladder cancer*, its knowledge of the first bladder cancer claim made known to the company was in September 2010[55] – and further considering the first bladder lawsuit was filed during the summer of July 2011[56] – the PSC argues the timing of the destruction of Mr. Miyazaki's files to be highly questionable and this Court, on the face of the chronology above, cannot disagree. At the very least, clearly documents were being destroyed as late as 2011, in the face of an *actual* ***bladder cancer case*** having been made known to Takeda, and unquestionably, after the "general Actos® 'products liability' litigation hold"[57] of 2002.

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[53] *See* email from Takeda dated June 14, 2013 , attached as Exhibit 4 to the instant motion.

[54] *See* email from Takeda dated June 6, 2013 , attached as Exhibit 3 to the instant motion.

[55] The September 2010 claim was received on or about September 21, 2010 when a patient made a spontaneous adverse event report via telephone to the call center operated on Takeda's behalf by PPD, as explained in Takeda's "Response and Objections to Plaintiffs' Supplemental Interrogatory 1 Regarding 2010 Actor Bladder Cancer Claim," attached as Exhibit 8 to "Plaintiff's Supplemental Memorandum in Support of Motion to Compel

The PSC argues the foregoing custodians, as well as other custodians whose documents were destroyed, were all individuals whose titles, themselves, indicate involvement with critical information regarding the development and marketing of Actos, and therefore, whose documents, electronic and otherwise, should reasonably be expected to reflect information critical to the plaintiffs' cases. The PSC argues many of these individuals should have been aware, *given their titles and roles within the companies*, or actually were aware, of the very risks now alleged to be associated with Actos. The PSC, therefore, argues the witnesses whose files were destroyed were not peripheral to the issues in this case, but rather, were at the heart of the corporate discussions about ACTOS, its development and risks, and, specifically – and most importantly – the need to "manage" those risks. The PSC further argues that based on the small sample of documents that escaped destruction and of which the PSC has had benefit of review, this Court should find the missing evidence to have been of a nature favorable to the plaintiffs in this case, as it concerned knowledge about bladder cancer long before warnings were provided,

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Fed.R.Civ.P. Rule 30(b)(6) Deposition on Litigation Hold Issue, [Doc. 3182], at p.4.

[56] Takeda admits in its opposition brief that the first bladder cancer lawsuit was filed in July 2011. *See* Takeda's opposition brief, Doc. 3530, at p. 1.

[57] *See* "Takeda's Response and Objections to Plaintiffs' Supplemental Interrogatory 2," attached as Exhibit 15 to the instant motion, Doc. 3484-2, at p. 4.

and illustrates a conscious attempt by Takeda to conceal and downplay such risks.

Despite conceding the "loss" of the forty-six custodial files, while at the same time arguing hundreds of thousands of pages of documents associated with the employees whose files are missing actually have been produced in other fashion and source,[58] Takeda primarily focuses its argument on its contention that *it owed no duty to preserve documents associated with "bladder cancer" litigation prior to the summer of 2011*, when Takeda argues it first *reasonably* anticipated *bladder cancer* litigation. The Court finds Takeda's argument unpersuasive for the following reasons. First, as noted herein, Takeda argues it was not aware of *bladder* cancer litigation associated with Actos until the filing of the first actual bladder cancer lawsuit in July 2011, and thus, Takeda contends it had no duty to preserve documents relating to Actos and *bladder* cancer. However, the foregoing argument is undercut by the fact that Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc., nonetheless, ***chose to institute a litigation hold sweeping in its scope and breadth, and containing no such limitation to or identification of a particular malady, in 2002***. The 2002 Litigation Hold is, by its own language, sweeping in nature and instructed to be broadly interpreted to encompass "any and all documents and electronic data which discuss, mention, ***or relate to Actos***."[59] Takeda's own language in no way limits the hold to, or references in any fashion, one specific malady above any other; rather, the scope is defined as that "which discuss, mention, **or relate to Actos**" and specifically instructs the hold **is to be interpreted "in its broadest sense."** Indeed, the 2002 Litigation Hold in no way limits the hold to documents relating to liver cancer, as has been argued by Takeda, but rather, *keys to the involved drug*, Actos, and uses broad and inclusive language instructing Takeda's employees to preserve documents relating to Actos. It is hard for this Court to imagine more inclusive language for purposes of a litigation hold, entrapping within its embrace "any and all documents . . . [related] to Actos;" exhorting employees to construe the hold in its "broadest sense;" and cautioning all employees not to "destroy, delete, throw away or otherwise discard any such documents or electronic data." The 2002 Litigation Hold, also, of significance, has never been lifted, and indeed, according to Takeda, has been "refreshed" at least five times, on September 17, 2003, May 4, 2006, October 22, 2007, January 14, 2008, and February 15, 2011.[60]

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[58] While this Court understands Takeda's emphasis on the number of pages of documents that it has produced in this case - some 33 million pages - the relevance to this Court of this large and impressive number is somewhat limited within the immediate context of this motion. Takeda's acknowledged enthusiasm in producing documents is, in the context of the instant motion, somewhat mitigated by its widespread failure to preserve large swaths of Actos-related documents generated and held by some very high-ranking officials.

[59] *See* 2002 Litigation Hold, attached as Exhibit 13 to the instant motion.

Second, and perhaps equally significant, Takeda has admitted TPC (Takeda Japan) *was aware of the 2002 Litigation Hold at the time of initial dissemination. Takeda* ***U.S.*** *notified three employees of Takeda* ***Japan*** *– Saburo "Sam" Hamanaka, Teruyuki "Terry" Fukumoto, and Masatake Kashiyae – of the 2002 Litigation Hold on or about July 19, 2002.*[61] Furthermore, Takeda admits *the 2006 "refresher" of the 2002 Litigation Hold was made accessible to the*

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[60] *See* Declaration of Stacey Dixon Calahan, attached as Exhibit 3 to Takeda's opposition brief, Doc. 3530, at ¶13., and "Takeda's Verified Response to Plaintiffs' Discovery Requests served September 23, 2013, as Amended September 24, 2013, with Question 1A" attached as Exhibit 14 to the instant motion, at p. 3. The PSC argues Takeda's duty to preserve arose as early as 2000 when Takeda began receiving product liability "claims" related to ACTOS. However, because Takeda admits it implemented the 2002 Litigation Hold, and because the majority of "lost' documents were "destroyed" after this date, for these purposes only, this Court need not address whether Takeda should have implemented a litigation hold two years earlier.

[61] *See* "Takeda's Verified Response to Plaintiffs' Discovery Requests Served September 23, 2013, as Amended September 24, 2013, With Question 1A," attached as Exhibit 14 to the instant motion, at p. 2.

***European** Takeda entities* through a Takeda company intranet site in April or May of 2006.[62] Thus, not only were Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. aware of the broad hold put in place in 2002, TPC (Japan) was made aware of the hold as of 2002, and the European Takeda entities were made aware of the hold as of 2006. Thus, the Takeda entities in the U.S., Europe and Japan were aware of the 2002 hold, respectively Takeda Japan - 2002, Takeda Europe - 2006.

Thus, the factual and legal significance of Takeda's argument that its first *reasonable* anticipation of *bladder cancer* litigation was in July 2011 is undercut both by its own broad language used in the 2002 hold as well as its multiple "refreshers," and calls into serious question both the timing and the handling of Mr. Miyazaki's data. Additionally, and in this Court's opinion, perhaps determinative of the issue is that Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc., for whatever reason and upon whatever knowledge, **actually instituted a broad and sweeping litigation hold in 2002 and gave notice of this hold to Takeda Japan in 2002 and Takeda Europe in 2006**. Thus, the reality of an instituted hold undercuts Takeda's arguments as to when they *should* or *should not have* instituted a litigation hold; the fact is *Takeda did institute a litigation hold* by its own language of sweeping breadth in 2002.

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[62] *See* "Takeda's Verified Response to Plaintiffs' Discovery Requests served September 23, 2013, as Amended September 24, 2013, with Question 1A" attached as Exhibit 14 to the instant motion, at p.3, as follows.

> 1A a. On what date did TGRD EU or any of the European Takeda entities first become aware of the July 19, 2002 legal hold?
>
> ANSWER: Takeda does not have a specific date when TGRD Europe (now known as Takeda Development Centre Europe, Ltd.) or the European Takeda Entities first became aware. TGRD Europe had access to the July 19, 2002 legal hold, in the form of the 2006 refresh notice, when the 2006 refresh notice was posted to Takeda's Horizon intranet site in April or May 2006. To the best of Takeda's knowledge and belief, no other European Takeda entity was aware of the July 19, 2002 legal hold before then.

The PSC has suggested the February 2010 "refresh" of the 2002 Litigation Hold was implemented after, and because of, the September 2010 bladder cancer "claim" (not a lawsuit), however, it is evident from Mr. Regard's testimony that Takeda has attempted to distance itself from this notion, suggesting the February 2011 "refresh" was implemented "because it had been so long since a refresh had been issued." *See* Deposition of Mr. Regard, at pp. 680-81.

Moreover, Takeda's secondary argument that the 2002 Litigation Hold should not be recognized by the Court on grounds the issuance of various legal holds on the various continents is not simultaneous – and therefore, not all of the Takeda entities were necessarily aware of the 2002 Litigation Hold in 2002 – is unpersuasive *as evidence shows* that *Takeda USA, **in fact**, put the Japanese Takeda entities on notice of the sweeping 2002 Litigation Hold immediately following the implementation of this hold, and the European Takeda entities were, **in fact**, put on notice of the 2002 hold in 2006.*[63] It is not disputed each of the relevant identified Takeda entities bore some involvement of some nature, with Actos; what that involvement might actually have been, however, is at the very least not necessarily agreed upon by the parties.[64] Nonetheless, the evidence establishes, and Takeda admits, Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. issued a hold in 2002; Takeda Japan was given notice of the hold in 2002; and Takeda Europe was given notice of the 2002 hold in 2006. For this reason, this Court concludes all of the U.S. and Japanese Takeda entities knew or "should have known" litigation involving Actos was either anticipated or reasonably foreseeable when the 2002 Litigation Hold was implemented in July 2002 and the Takeda European entities in 2006. It begs the question to now debate *whether* Takeda should have *reasonably anticipated* litigation as to Actos, for "personal injury and wrongful death" as noted within the language of the 2002 hold, as the 2002 hold declares, *Takeda clearly knew* of litigation grounded upon claims for "personal injury and wrongful death" arising out of Actos in 2002, and they issued a sweeping litigation hold in 2002, and instructed the hold be interpreted "in its broadest sense."

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[63] *See* "Takeda's Verified Response to Plaintiffs' Discovery Requests Served September 23, 2013, as Amended September 24, 2013, With Question 1A," attached as Exhibit 14 to the instant motion, at pp. 2-3.

[64] However, for purposes of the *Allen* trial, only, the stipulation found at Doc. No. 512 [12-cv-00064 and Doc. No. 3880 [MDL No. 6:11-md-2299] instructs all Takeda entities are to be considered one juridical entity.

Over the unfortunate course of discovery, Takeda has made an ever-shifting argument as to the nature, importance, and character of the 2002 hold and its self proclaimed "refreshers." Takeda's argument that the 2002 Litigation Hold does not apply to *general products liability litigation* – and applies only to *liver cancer* – is similarly entitled to little weight. The hold, on its face and pursuant to its clear and unambiguous language, in no way limits itself to a specific malady, but rather, ties itself to the drug involved, *i.e.* Actos, and notes it is being put into place because of litigation for "personal injury and wrongful death . . . allegedly resulting from use of . . . Actos," and Takeda, itself, refers to the 2002 hold as a "general hold."[65] Again, it cannot be overlooked that by its own clear and unambiguous language, the 2002 Litigation Hold is sweeping in scope, is instructed to be broadly interpreted, and, also, instructs Takeda employees to preserve "any and all documents and electronic data ***which discuss, mention, or relate to Actos.***" Takeda's after-the-fact attempt, when facing over 6,000 lawsuits across the country for bladder cancer allegedly arising out of the use of Actos, to read into the 2002 hold, limitations not found in its clear language and instruction is highly suspect, at best.

Furthermore, from this Court's reading of the record, it appears Takeda has indirectly noted a distinction between "claims" and "lawsuits" and has, thereby, embraced the September

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[65] *See* "Takeda's Response and Objections to Plaintiffs' Supplemental Interrogatory 2," attached as Exhibit 15 to the instant motion, Doc. 3484-2, at p. 4.

2010 "claim" (but not lawsuit) for *bladder* cancer as falling under the 2002 Litigation Hold, the significance of which is apparent. When one traces *the language and progression* of the various litigation holds issued by Takeda with respect to Actos, the following is clear:

- As this Court has noted, the language of the **2002 Litigation Hold** requires the recipient to "preserve any and all documents and electronic data which discuss, mention, or related to Actos." The language of the hold itself mentions that the hold is being implemented because Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. are now defendants in a "**lawsuit**" alleging "personal injury and wrongful death."

- In 2006, Takeda issued a document entitled "Legal Hold Related to Actos Products Liability Claims" (the **"2006 Litigation Hold"**), which states:

  Takeda continues to be involved in a small number of **claims or lawsuits ("claims")** relating to ACTOS®. . . As a result of these **claims**, all documents, materials, information and things that exist or continue to be developed *pertaining to ACTOS®* **have been and continue to be** subject to a Legal Hold. . . . **This means that all documents, materials, and computer files (including e-mails, word processing documents, slides, etc.) falling into this category must continue to be maintained until you are informed otherwise . . .**[66]

- In 2011, Takeda issued yet another document, entitled "Actos Product Liability Legal Hold" (the **"2011 Litigation Hold"**), which states:

  Takeda Pharmaceuticals North America, Inc. continues to be involved **in product liability claims** *regarding ACTOS®*. As a result, for these **claims**, Takeda must take steps to ensure the preservation of all documents, as defined below, relating to this matter. . . . All documents that relate to **these claims** that you now possess or that come into your possession in the future must be preserved even if they would normally be destroyed in the ordinary course under Takeda's document retention policy. . . .

The foregoing document goes on to describe a variety of documents that must be

[66] *See* document entitled "Legal Hold Related to Actos Products Liability Claims," attached as Exhibit 20 to the instant motion (ceratin emphasis added; certain emphasis in original).

preserved, including, but not limited to, "*[d]ocuments relating to the safety or efficacy of ACTOS* or ACTOS combination medicines," and "[d]ocuments relating to the research and development of ACTOS or ACTOS combination medicines."

- In Takeda's 30(b)(6) deposition, with respect to the 2006 Litigation Hold (as well as the 2007 Litigation Hold, the language of which this Court has not been supplied), Mr. Regard testified as follows:

  Q: Okay. Well, the point we're getting to here is, the February hold, the February 2011 hold that Ms. Calahan distributed –

  A: Yes, sir.

  Q: – the language changed significantly, did it not, from the 2006 and 2007 version, which were the same?

  A: It looks to be very different, yes.

  Q: Okay. So why – when you talked to Ms. Calahan, when she said she was – this was just some sort of refresh unrelated to any bladder cancer or any particular event, why did she completely redraft the hold?

  A: I did not ask her that question.

  Q: Why not? Why didn't you ask her that?

  A: It didn't occur to me at the time to ask her.[67]

Thus, Mr. Regard testified that Ms. Calahan stated the 2011 Litigation Hold (apparently written by Ms. Calahan) was simply a "refresh" of the 2002 Litigation Hold.[68] However, when asked why the 2011 hold was "re-drafted," Mr. Regard responded that – inexplicably – he did not ask Ms. Calahan why she re-drafted the 2011 Litigation Hold. What becomes apparent when one tracks the evolution of the various litigation holds supplied to this Court by the parties, is that despite re-writing the Actos litigation hold in 2011, Ms. Calahan, according to Mr. Regard, identifies it as a "refresher," and the language itself reflects no limitations on the documents to be preserved, and did not, for instance, limit the 2011 Litigation Hold to "liver cancer" or now embrace "bladder cancer." If anything, Ms. Calahan broadened the language of the 2011 Litigation Hold to include all **claims**, when the 2006 (and, presumably, 2007) Litigation Hold referred to **"claims or lawsuits"** and the 2002 hold referenced a **"lawsuit."** Thus, the evolution of the language of the various Actos litigation holds shows the breadth and substance of the holds has never been limited, rather, if anything, has been broadened, from a "lawsuit" in 2002, to "claims and lawsuits" in 2006, and to "claims" in February 2011.[69] And, as Ms. Calahan herself has stated – according to Mr. Regard – the 2011 Litigation Hold is merely a refresh of the 2002 Litigation Hold.

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[67] *See* Deposition of Daniel Regard, at pp. 782-83.

[68] The Court has not been provided all exhibits to Mr. Regard's deposition. Although it is unclear on what actual date the July 2011 lawsuit was filed, the February 2011 Litigation Hold was issued on February 15, 2011. *See* February 15, 2011 e-mail from Stacey Calahan to "Colleagues," attached as Exhibit 9 to the instant motion.

The foregoing, again, becomes apparent when reviewing the evolution of the language of various litigation holds, themselves, as well as Mr. Regard's deposition testimony, when considered in context with the following Takeda response to certain written discovery, which states:

> . . . the "**2010 Claim**" was received on or about September 21, 2010, when a patient made a spontaneous adverse event report via telephone to the call center operated on Takeda's behalf by [PPD]. . . . The patient who communicated the "2010 Claim" to PPD **did not file a lawsuit** seeking compensation for bladder cancer allegedly caused by Actos® **until July 2012**, at which time a complaint naming Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceutical Company Limited was filed in the Circuit Court of Cook County, Illinois. . . . The attorneys and law firms representing Takeda [in the instant MDL litigation] began representing Takeda with respect to the

[69] The 2010 claim was a bladder cancer claim, followed afterward by a July 2011 lawsuit for bladder cancer.

> "2010 Claim" in July 2012, at the time the patient who communicated the "2010 Claim" to PPD filed and served a lawsuit in Cook County, Illinois seeking compensation for bladder cancer allegedly caused by Actos®. . . .**A general Actos® "product liability" litigation hold was in place at Takeda Development Center Americas, Inc. . . . Takeda Pharmaceuticals U.S.A., Inc. . . . and Takeda Pharmaceuticals America, Inc. at the time the "2010 Claim" was received, and was refreshed in February 2011 after the "2010 Claim" was received.**[70]

Additionally, in discussing the same 2002 Litigation Hold in her "Declaration," Ms. Calahan states "

> Takeda entities in the United States **have refreshed the July 19, 2002 Actos-related legal hold at various times (e.g., September 17, 2003; May 4, 2006; October 22, 2007; January 14, 2008; February 15, 2011).**[71]

Thus, it would seem, the 2010 bladder cancer claim came under the general litigation hold – implemented in 2002 and "refreshed" thereafter -- and the 2010 claim was for bladder cancer, not liver cancer, which further undercuts Takeda's current argument that the 2002 Litigation Hold should be read, despite its clear language, to apply only to liver cancer claims.

Again, the actual language Takeda chose to incorporate to create the 2002 Litigation Hold is clear; the sweep broad; the scope grand; and keys to the drug involved - Actos - and not any specific malady; and the added instruction is given within the hold itself to interpret the hold "in its broadest sense." Consequently, Takeda's attempt to alter the clear and unambiguous language and instruction of the hold in the face of its clear language of the hold, itself, and the evolution of the holds, is wholly unpersuasive.

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[70] *See* "Takeda's Response and Objections to Plaintiffs' Supplemental Interrogatory 1 Regarding 2010 Actor Bladder Cancer Claim," attached as Exhibit 8 to "Plaintiff's Supplemental Memorandum in Support of Motion to Compel Fed.R.Civ.P. Rule 30(b)(6) Deposition on Litigation Hold Issue, [Doc. 3182], at p.4-5. (emphasis added).

[71] *See* "Declaration of Stacey Dixon Calahan," p. 3, attached as Exhibit 3 to Takeda's responsive brief [Doc. 3530] (emphasis added).

Takeda's related argument that reasonable anticipation of other Actos-related products liability litigation did not give rise to a duty to preserve evidence related *to the bladder cancer plaintiffs involved in this multi-district litigation* is specious, at best. In support of this argument, Takeda cites this Court to several cases in which courts considered a "shifting duty" of preservation.[72] For example, in *Point Blank Solutions, Inc. v. Toyobo America, Inc.*, 2011 WL 1456029 (S.D. Fla. Apr. 5, 2011), the court, in that matter, held the duty to preserve potentially relevant evidence arises when the party in possession of the evidence knows litigation by the party seeking the evidence – as opposed to a third party – is pending or probable. In so holding, the court noted a separate lawsuit *by a third party* or a subpoena *issued by the government* did not prove the defendant reasonably anticipated litigation *with the plaintiff in that lawsuit*. In effect, the court declined to allow the plaintiff to take advantage of an evidence-preservation duty owed by the defendant to a third party or different government agencies. 2011 WL 1456029 at *25-26.

Point Blank Solutions, and other cases addressing a "shifting duty" of preservation, is inapplicable in the instant case. "Shifting duty" cases involve a claimant seeking the benefit of a previously-issued hold *not issued for his or her benefit*, here the 2002 hold, by its own language, was prompted by the filing of a lawsuit alleging "personal injury or wrongful death . . . resulting from the use of . . . Actos." Plaintiffs in this MDL, each allege personal injuries and/or wrongful death "resulting from the use of . . . Actos." The scenario presented in *Point Blank Solutions* is simply not similar to the scenario presented in the instant case. Here, a defendant manufacturer,

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[72] In support of this contention Takeda cites to three cases: *Point Blank Solutions, Inc. v. Toyobo America Inc.*, No. 09-61166-CIV, 2011 WL 1456029, at *24-25 (S.D. Fla. Apr. 5, 2011) (M.J. Goodman); *Stanfill v. Talton*, 851 F.Supp.2d 1346, 1365 (M.D.Ga.2012) (J. Treadwell); and *In re Delta/Airtran Baggage Fee Antitrust Litigation*, 770 F.Supp.2d 1299, 1308 (N.D.Ga.2011) (J. Batten).

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in 2002, issued and "refreshed" multiple times thereafter, by its own admission, a *general products liability hold* sweeping in its breadth, and *applicable to a specific drug, Actos*. The cases within this MDL all grow out of and/or relate to products liability claims for wrongful death or personal injury allegedly resulting from the use of the same drug (Actos), thus, clearly distinguishing the instant matter from the cases argued by Takeda. The 2002 Litigation Hold has been in place and "refreshed" over approximately twelve years and, thus, has been addressing those injuries allegedly resulting from Actos, including injuries to the liver, heart, and bladder as well as syncope claims;[73] here the claimants in this MDL are all claimants whose particular injuries are alleged to result *from use of Actos*, **the drug upon which the hold is founded**. Takeda's argument is, therefore, unpersuasive.

Again, for the reasons noted, this Court concludes the clear, express, and unambiguous language of the 2002 Litigation Hold and its "refreshed" incarnations all contain broad language without limitation to or distinction between or among specific maladies and, therefore, embrace the bladder cancer claimants who are plaintiffs in the instant MDL, therefore, this Court finds the duty to preserve documents relevant to the claims of these bladder cancer plaintiffs arose in 2002, ***when Takeda chose*** to, and ***in fact, did issue*** a broad and sweeping litigation hold, which, by its own admission, it "refreshed" up to and including 2011. Furthermore, this Court finds Takeda of Japan had notice of the hold in 2002 and Takeda of Europe in 2006, and as it is undisputed those Takeda entities were associated with Actos, they, too, were subject to the sweeping hold put in place.

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[73] *See* "Attachment A to Takeda's Response to Plaintiffs' Supplemental Interrogatory No. 2," attached as Exhibit 6 to the instant motion.

This Court finds it need not determine ***when Takeda should have implemented*** a hold because Takeda, **in fact, did implement a hold in 2002** and "refreshed" it thereafter. Thus, whether Takeda now wishes to argue whether it knew or should or should not have known or should or should not have implemented a hold is of little legal or factual import as the inescapable fact is that **Takeda *did* implement a hold in 2002 and, "refreshed" it over the years and by its own words, did so, initially, because it knew...** "a motion has been filed to add Takeda Pharmaceutical North America, Inc. and Takeda Pharmaceutical America, Inc. **as Defendants in a lawsuit** . . . " (emphasis added). Takeda thereby certainly had its requisite "reasonable anticipation" in 2002 and the evolving language of the subsequent "refreshers" cites, respectively, "claims or lawsuits" year 2006 and "claims" year 2011.

Nor is it lost on this Court that Takeda, itself, chose the language of the 2002 Litigation Hold; language that was originally put in place in response to a lawsuit for "damages for personal injury and wrongful death . . . allegedly resulting from use of . . . Actos" and instructed employees "to preserve any and all documents and electronic data which discuss, mention, *or relate to Actos*" and to "interpret this directive in its broadest sense to prevent the deletion or destruction of *any recorded information and data relating in any way to Actos*." It, equally, is not lost on this Court that the 2002 Litigation Hold was "refreshed" at least 5 times, rather than being replaced by a new hold keying not to the drug, but one specifically tailored to discrete injuries, as now argued by Takeda. In sum, this Court finds that as of the date the hold was issued in 2002, Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc., as well as Takeda Japan, had the duty to preserve "any and all documents and electronic data which discuss, mention or relates to Actos" and as of 2006, once Takeda Europe was made aware of the hold, Takeda Europe had the same duty. Therefore, this Court concludes all evidence "destroyed" or "lost" or rendered inaccessible for any reason, after the 2002 Litigation Hold was put in place, constitutes spoliated evidence for the purposes of this motion as to Takeda, Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. ,Takeda Japan, and as of 2006, Takeda Europe. As this Court, also, finds certain documents and electronic data were "lost," destroyed," or "rendered inaccessible" by Takeda after the hold was to apply, this Court, therefore, finds a duty to preserve existed, and that duty was clearly breached.

B. *Sanctions*

District courts addressing this question agree, once a court has determined evidence was spoiliated, the court may, but is not compelled to, exercise its discretion to impose sanctions upon the responsible party, under its inherent authority. In exercising its discretion, district courts agree, a court should evaluate: (1) the degree of fault of the party who altered or destroyed the evidence; (2) the degree of prejudice suffered by the opposing party; and (3) whether there is a lesser sanction that will avoid substantial unfairness to the opposing party. *Alcoa, supra* at 340, *citing Menges v. Cliffs Drilling Co.,* 2000 WL 765082, *6 (E.D. La. 2000). In District Courts within the Fifth Circuit, as a general rule, the "severe sanctions of granting default judgment, striking pleadings, or giving adverse inference instructions may not be imposed unless there is evidence of 'bad faith.'" *Rimkus*, *supra* at 614, *citing Condrey v. SunTrust Bank of Ga.*, 431 F.3d 191, 203 (5th Cir. 2005); *King v. Ill.Cent. R.R.*, 337 F.3d 550, 556 (5th Cir. 2003); *United States v. Wise*, 221 F.3d 140, 156 (5th Cir.2000). Overriding the foregoing analysis is the caution counseled by the United States Supreme Court when a Court proceeds to impose sanctions pursuant to its inherent power, and the jurisprudential suggestion that when imposing sanctions, the sanction should be only that necessary to redress conduct that abuses the judicial process. *See Silvestri v. General Motors Corp.*, 271 F.3d 583, 590 (4th Cir. 2010), *citing Chambers*, *supra* at 45-46.

Chief, and most immediate in its possible application as to *Allen,* among the sanctions sought by the PSC is an adverse inference instruction for the jury. Again, district courts agree, a party seeking the sanction of adverse inference based on the spoliation of evidence has the burden to establish the following: (1) the party with control over the evidence had an obligation to preserve it at the time it was destroyed; (2) the evidence was destroyed with a culpable state of mind; and (3) the destroyed evidence was "relevant" to the party's claim or defense such that it would support that claim or defense. *Alcoa, supra* at 340, *citing Zubulake IV*, 220 F.R.D. at 220. *See also Residential Funding Corp. v. Degeorge Fin. Corp.,* 306 F.3d 99, 107 (2nd Cir.2002). The "relevance" and "prejudice" factors are often conflated, however, and, perhaps, can better be understood when broken down into three sub-parts: "(1) whether the evidence is relevant to the lawsuit; (2) whether the evidence would have supported the inference sought; and (3) whether the non-destroying party has suffered prejudice from the destruction of the evidence." *Rimkus*, 688 F.Supp.2d at 616.

1. Duty to preserve

The first factor in an adverse inference analysis is whether the party with control over the evidence had an obligation to preserve evidence at the time the evidence was destroyed. This Court has determined Takeda had a duty to preserve "any and all documents and electronic data which discuss, mention, or relate to Actos" beginning in July 2002, at the time Takeda implemented the 2002 Litigation Hold in both the United States and Japan, and in 2006 in Europe. Thus, for the reasons given, this Court has found that no later than July 2002, Takeda had an obligation to preserve documents and information – including electronically stored information – relevant to the plaintiffs' claims alleged in this MDL in the United States and Japan and as of 2006 in Europe for all cases. Takeda has admitted 38 of the 46 custodial files at issue were either lost, destroyed, or otherwise rendered inaccessible after the implementation of the 2002 Litigation Hold. Consequently, this Court finds the PSC has carried its burden as to the first factor.

2. Relevance and prejudice

The Court next looks to whether the missing evidence was "relevant" to the PSC's claims and/or defenses such that it would support those claims and/or defenses. As noted, this inquiry often is conflated with the issue of prejudice, however, courts have broken – and this Court will break – the issues of relevance and prejudice into 3 sub-parts: "(1) whether the evidence is relevant to the lawsuit; (2) whether the evidence would have supported the inference sought; and (3) whether the non-destroying party has suffered prejudice from the destruction of the evidence." *Rimkus*, 688 F.Supp.2d at 616. District courts recognize, and this Court agrees, "[t]he burden placed on the moving party to show that lost evidence would have been favorable to it ought not be too onerous, lest the spoliator be permitted to profit from its destruction." *Rimkus*, 688 F.Supp.2d at 616, *citing Chan v. Triple 8 Palace, Inc.*, 2005 WL 1925579, at *7 (S.D.N.Y. Aug 11, 2005) (M.J. Francis).

This Court is mindful of the unenviable task assigned to a party who does not have benefit of the very information it seeks to show would be relevant, and yet, is charged with the task inherent in arguing the importance of that unknown information, particularly when the party who was in possession of the same (now missing) information stands ready to oppose all its efforts to do so. The district court in *Rimkus* attempted to address this seeming "Catch-22" by addressing both sides of the argument:

> *Pension Committee* recognized the difficulty and potential for unfairness in requiring an innocent party seeking discovery to show that information lost through spoliation is relevant and prejudicial. Those concerns are acute when the party seeking discovery cannot replace or obtain extrinsic evidence of the content of deleted information. But in many cases—including the present case—there are sources from which at least some of the allegedly spoliated evidence can be obtained. And in many cases—including the present case—the party seeking discovery can also obtain extrinsic evidence of the content of at least some of the deleted information from other documents, deposition testimony, or circumstantial evidence.
>
> Courts recognize that a showing that the lost information is relevant and prejudicial is an important check on spoliation allegations and sanctions motions. Courts have held that speculative or generalized assertions that the missing evidence would have been favorable to the party seeking sanctions are insufficient. By contrast, when the evidence in the case as a whole would allow a reasonable fact finder to conclude that the missing evidence would have helped the requesting party support its claims or defenses, that may be a sufficient showing of both relevance and prejudice to make an adverse inference instruction appropriate.

688 F.Supp.2d at 616-17.

After analyzing the evidence set forth by the plaintiff in *Rimkus*, the district court suggested evidence obtained from third parties can often establish the potential relevance of destroyed evidence, to wit:

> Despite the evidence of spoliation and efforts to conceal it, the record also shows that Rimkus was able to obtain a significant amount of evidence. Rimkus had the laptop Bell used during his employment, although Rimkus delayed in examining it. That laptop revealed useful information about records Bell took from Rimkus. Although they deleted or destroyed the relevant emails, attachments, and documents on other computers, the defendants also produced numerous documents and emails relating to their communications and preparations to form

> U.S. Forensic. Rimkus was also able to obtain numerous emails from Homestead, which hosted all U.S. Forensic's emails between November 15, 2006 and December 19, 2006. And the defendants have subsequently, if belatedly, produced numerous responsive emails and documents relating to the formation of U.S. Forensic and the solicitation of Rimkus clients.

Id. at 644.

In the instant case, the record shows the PSC was able to identify the missing information, much of which was from individuals strategically placed within the Takeda corporate structure whose job titles imply knowledge of drug development and/or marketing during the relevant time period. The PSC, also, was able to obtain a significant amount of evidence through third parties, including, significantly, Upjohn, an entity that at one time was considering, but ultimately declined, a collaboration with Takeda on the Actos project.[74]

This Court notes the following communications, although not located in the custodial files of the either the sender or the recipient, were located in the files of other Takeda employees or

through third-party discovery:

- August 2005 email from Mick Roebel, Takeda Vice President of Regulatory Affairs, to (among others) Kiyoshi Kitazawa and Phillip Collett (Vice President of Regulatory Affairs at Takeda Global Research and Development Centre (Europe) Ltd.).[75] In this email, Mr. Roebel outlines the "Best Case Scenario," "Worst Case Scenario," and "Most

[74] Although it "lost," "deleted," or "destroyed" forty-six (46) custodial files, Takeda, also, produced numerous documents and e-mails relating to its communications concerning Actos. Indeed, portions of the missing files have been found in custodial files of other employees of "Takeda," which have been produced by Takeda. For example, although the files of Takashi Nonoyama, Associate Director, Pharmaceutical Research Division, Research Management Department, Planning & Development – including Mr. Nonoyama's e-mail account, personal file share, and personal computer – were erased, Mr. Nonoyama's successor, Mr. Masaki Yamamoto, remembers receiving some hard copy documents, and Mr. Yamamoto's documents relevant to Actos have been produced, therefore it is possible some of Mr. Nonoyama's are contained within Mr. Yamamoto's file and those have been produced .

[75] *See* August 8, 2005 e-mail, attached as Exhibit 25 to the instant motion.

Likely Scenario" concerning data connecting Actos to bladder cancer and the drug's labeling. The foregoing email was not located in Mr. Kitazawa's file [which is lost] but, rather, was found in the file of another Takeda employee.

- A series of emails dated January 2003 from Claire Thom to (among others) Mr. Kitazawa, discussing the marketing implications of labeling changes related to bladder cancer.[76]

- A September 22, 2004 email from David Eckland (Managing Director at Takeda Europe Research & Development Centre. Ltd.) to (among others) Masahiro Miyazaki, Phillip Collett, and Mr. Kitazawa. This email discusses the consequences of a medical paper describing pioglitazone as having a mixed gamma and alpha activity at clinical concentrations. Takeda has admitted losing the custodial files of all four of the [noted] e-mail's recipients.[77]

The potential relevance of the foregoing information is obvious, as that which was located relates to Takeda's knowledge about the potential health concerns of Actos as those concerns might relate to bladder cancer and the sufficiency of the company's warnings on its labeling. Thus, the PSC has located, from other sources, information which would have been in the deleted custodial files after the hold was put into place, which establishes those employees were involved with issues directly applicable to Plaintiffs' claims and which - if dealing with company implications related to Actos and bladder cancer - could be beneficial to plaintiffs' claims.

Perhaps the most compelling evidence of potential beneficial relevance and prejudice to Plaintiffs, however, is the correspondence of Tai Matsuzawa and Kiyoshi Kitazawa. Mr. Matsuzawa was a **Vice-President of the Pharmaceutical Group of Takeda Chemical**

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[76] *See* January 2003 e-mails, attached as Exhibit 26 to the instant motion.

[77] *See* September 2004 e-mail, attached as Exhibit 27 to the instant motion.

Industries, Inc. in Japan, while Mr. Kitazawa was a **Managing Director, Board Member, and General Manager of Takeda's Strategic Product Planning Department**, in Japan who worked for TPC from April 1, 1971 to June 25, 2009. Takeda has confirmed Mr. Kitazawa's e-mail account was deleted from active servers on October 1, 2009; his personal file share and all personal data was deleted by a Takeda IT vendor on January 28, 2010, pursuant to a request dated January 20, 2010; and his business documents were discarded at the time of his departure. Thus, all of the foregoing deletions were made *after the 2002 Litigation Hold was in place*.

Through third-party discovery with Upjohn, the PSC obtained correspondence from Dr. J.B. Mitchell, the president of Upjohn (as noted earlier Upjohn and Takeda were considering a collaboration on Actos in 1993), who wrote to Mr. Matsuzawa on September 21, 1993:

> On September 20 our Pharmaceutical Executive Council, Upjohn's highest scientific decision-making body, carefully reviewed the results of the toxicology and clinical studies. The decision of the Council was that Upjohn will not go forward with pioglitazone in the clinic. ***The Council decided that further clinical development of pioglitazone could not be justified based on their concern regarding pioglitazone's margin of safety***.[78]

One month later, on October 25, 1993, Dr. Kitazawa – whose files are missing – wrote to Dr. Patricia Ruppel, the Project Manager Director for Upjohn, as follows:

> Regarding Upjohn's statement for the development status of pioglitazone, **we would like to propose the following alternative or a similar [sic] instead of Upjohn's proposal in due consideration of our current development status.**
>
> In the very preliminary clinical evaluation in the U.S.A., ***pioglitazone did not show the reduction of blood glucose enough to satisfy Upjohn's in-house requirement***. Any considerable work that would be needed is not in line with our

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[78] *See* Letter from J.B. Mitchell to Tai Matsuzawa, dated September 21, 1993, attached as Exhibit 22 to the instant motion (emphasis added).

> business needs for further development of Pioglitazone. Hence, all development on pioglitazone at Upjohn has ceased.[79]

The foregoing correspondence reflects Upjohn withdrew from the Actos development deal with Takeda over issues of **"pioglitazone's margin of safety."** The Takeda correspondence one month later reflects Takeda's ***attempt to shift the Upjohn explanation*** and **omit Upjohn's express** ***safety concerns*** associated with Actos **and substitute** reference to concerns with the ***efficacy of Actos as a reducer of blood glucose.*** The PSC argues Takeda's direct attempt to shift the focus away from safety concerns to the less damaging efficacy concerns, as well as Takeda's blatant attempt **to eliminate** language referencing Upjohn's ***safety*** concerns from not only the language used, but the stated reason Upjohn expressed for withdrawing from the collaboration, is clear evidence of Takeda's culpable intent *to conceal* the expressed *safety concerns* Upjohn associated with Actos, and, therefore, is evidence of Takeda's bad faith, and goes to the heart of the plaintiffs' failure to warn claims.

That the foregoing evidence is relevant to the plaintiff's failure to warn claims cannot seriously be disputed. The efficacy of Actos as a drug for the treatment of diabetes and the safety of Actos as a drug to be marketed to the public are two separate aspects of the drug. Indeed, a drug may be wonderfully effective as a treatment for the medical problem for which it was developed, but, also, be highly toxic or deadly to the individual taking it, and the applicable New York law governing the *Allen* claim imposes a duty on a drug's manufacturer to warn of "all potential dangers." Upjohn declined to go forward with the development of Actos in the clinic and clearly stated its specific concern and its reasons for so declining: "Upjohn's **highest**

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[79] *See* Letter from K. Kitazawa of Takeda to Patricia L. Ruppel, Director of Project Management at Upjohn, dated October 25, 1993, attached as Exhibit 23 to the instant motion (emphasis added).

scientific decision-making body" had reviewed results of "the toxicological and clinical studies" and **determined "Upjohn will not go forward with pioglitazone . . . . based on their concern regarding pioglitazone's margin of safety.**" (emphasis added) Nonetheless, and in the face of Upjohn's scientific assessment and stated safety concerns, *Takeda attempted to convince Upjohn to abandon their "margin of safety" language in favor of language keying to pioglitazone's efficacy*, *i.e.*, thus, wholly omitting any reference to concerns of Actos' "margin of safety" and substituting in its place language keying to efficacy, *i.e.*, pioglitazone did not reduce blood glucose well enough to satisfy Upjohn. Clearly, based on the evidence presented by the PSC, Upjohn sought to disengage from the Actos project **for safety concerns**. Yet Mr. Kitazawa - ***a General Manager at Takeda Japan's Pharmaceutical Development Division***, and, therefore, a highly-placed corporate employee, who was speaking on behalf of Takeda with Upjohn - attempted to have Upjohn omit language reflecting Upjohn's safety concerns and substitute language concerning the efficacy of the drug as a blood glucose reducer, **a totally separate and much less damaging concern.**

Clearly, Mr. Kitazawa - whose files are missing - was at the very least *speaking on behalf of his employer Takeda when he wrote to the Project Manager for Upjohn*, and thus, it is not unreasonable to assume Mr. Kitazawa's attempt to omit language of safety and substitute language of efficacy reflected Takeda's corporate position and corporate culture on this issue. That the missing files could evidence a corporate culture embracing attempts to remove mention of or an attempt to conceal or underplay expressed safety concerns surrounding the development of Actos is strongly suggested, if not fully established by this interchange.

Again, this Court is not unaware of the difficulty of the task at hand in attempting to determine *the true nature of Takeda's conduct* in relation to the duty to preserve information. As Judge Rosenthal suggested in *Rimkus*:

> It can be difficult to draw bright-line distinctions between acceptable and unacceptable conduct in preserving information and in conducting discovery, either prospectively or with the benefit (and distortion) of hindsight. ***Whether preservation or discovery conduct is acceptable in a case depends on what is reasonable, and that in turn depends on whether what was done—or not done—was proportional to that case and consistent with clearly established applicable standards***. As Judge Scheindlin pointed out in *Pension Committee*, that analysis ***depends heavily on the facts and circumstances of each case*** and cannot be reduced to a generalized checklist of what is acceptable or unacceptable.

688 F.Supp.2d at 613 (emphasis added).

Considering the foregoing, this Court concludes the plaintiffs have made a sufficient showing of relevance and prejudice.

3. Culpability of mind, i.e., "bad faith"

The PSC requests a variety of sanctions for the conduct of Takeda, the most serious of which are a default judgment or an adverse inference at trial. Because the issue and/or degree of "bad faith" is so hotly contested in this litigation and so pivotal to the issue of the remedy to be granted, the Court will discuss the caselaw and analysis in some depth.

Generally, the jurisprudence instructs that to obtain even the less serious sanction of an adverse inference, a party seeking such sanction must establish the evidence in question was destroyed with a "culpable state of mind." *Alcoa,* 244 F.R.D. at 340, *citing Zubulake IV*, 220 F.R.D. at 220. In the Fifth Circuit, the imposition of severe sanctions for spoliation, also, requires a showing of bad faith. *See, e.g., Condrey v. SunTrust Bank of Georgia*, 431 F.3d 191, 203 (5th Cir. 2005) ("The Fifth Circuit permits an adverse inference against the destroyer of evidence only upon a showing of "bad faith" or "bad conduct.); *King v. Illinois Cent. R. R.*, 337

F.3d 550, 556 (5th Cir. 2003) ("An adverse inference based on the destruction of potential evidence is predicated on the "bad conduct" of the defendant."); *Ford v. Potter*, 354 Fed. Appx. 28, 33 (5th Cir. 2009) (unpublished) (" . . . an [adverse] inference is predicated on the "bad conduct" of the defendant."); *United States v. Wise*, 221 F.3d 140, 156 (5th Cir. 2000) ("An adverse inference drawn from the destruction of records is predicated on bad conduct"); *Vick v. Texas Employment Com'n*, 514 F.2d 734 (5th Cir. 1975) ("The adverse inference to be drawn from destruction of records is predicated on bad conduct of the defendant. Moreover, the circumstances of the act must manifest bad faith. Mere negligence is not enough, for it does not sustain an inference of consciousness of a weak case.").[80]

This Court's exhaustive research has shown the majority of cases addressing the discreet issue of bad faith spoliation are either unpublished, do not address the issue within the context of the spoliation of electronically stored information, or do not set forth a framework under which to analyze the varying degrees of culpable conduct which might be sufficient to trigger the severe remedy of an adverse inference or the varying degrees of other appropriate remedies. Indeed, the analysis appears to be highly fact-based, requiring a court faced with the issue of sanctions to reconcile the conduct of the spoliator with a sanction that appropriately – but not unnecessarily severely – punishes the conduct. Because such issues relating to discovery are primarily handled at the district court level, the lack of Fifth Circuit appellate caselaw setting forth a comprehensive framework for the bad faith analysis is not surprising. Consequently, again, this Court will look to the experiences of its sister courts for guidance and experience within which to analyze the issue of bad faith. In so doing, this Court is, also, and always must be mindful of the jurisprudential overlay of caution set forth by the United States Supreme Court in *Chambers*, *i.e.*, and the exhortation to "exercise caution in invoking its inherent power" to sanction, *Chambers*, 501 U.S. at 50, as well as the need to employ "the least possible power adequate to the end proposed." *Natural Gas Pipeline Co. Of America v. Energy Gathering, Inc.*, 86 F.3d 464 (5th Cir. 1996) .

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[80] As pointed out in *Rimkus*:

> Other circuits have also held negligence insufficient for an adverse inference instruction. The Eleventh Circuit has held that bad faith is required for an adverse inference instruction. The Seventh, Eighth, Tenth, and D.C. Circuits also appear to require bad faith. The First, Fourth, and Ninth Circuits hold that bad faith is not essential to imposing severe sanctions if there is severe prejudice, although the cases often emphasize the presence of bad faith. In the Third Circuit, the courts balance the degree of fault and prejudice.

688 F.Supp.2d at 614 (internal citations omitted).

A review of the district court-level jurisprudence on this issue shows the enlightened concept of a range, or continuum, of both conduct and remedy. In *Ashton v. Knight Transp., Inc.*, the district court discussed the varying degrees of culpability of a spoliator, as follows:

> ***Courts have not been uniform in defining the level of culpability—be it negligence, gross negligence, willfulness, or - that is required before sanctions are appropriate for evidence destruction***. Nonetheless, an in-depth discussion of the varying levels of blameworthiness required to trigger sanctions for spoliation is not necessary here for two reasons. First, the Court is proceeding pursuant to its inherent authority, which is necessarily confined "to instances of bad faith or willful abuse of the judicial process." Second, Plaintiff seeks an adverse inference jury instruction or the striking of Defendants' pleadings for their conduct in this case, both of which require a showing of bad faith on the part of the Defendants.
>
> [. . .]
>
> The term "bad faith" has been described as conduct involving "fraudulent intent and a desire to suppress the truth." Another court described "bad faith" as "destruction for the purpose of depriving the adversary of the evidence." The Fifth Circuit has instructed that an adverse inference jury instruction for spoliation is appropriate where a showing is made that the malfeasant party "intentionally destroy[ed] important evidence in bad faith [and] did so because the contents of those documents were unfavorable to that party." ***Allowing that***

> ***there are myriad scenarios involving allegations of evidence destruction, one legal certainty, in the Fifth Circuit, is that "the circumstances of the act [of spoliation] must manifest bad faith" before severe sanctions are available.***

772 F.Supp.2d at 800-01 (emphasis added) (internal citations omitted).[81]

In *Rimkus*, Judge Rosenthal further elaborated:

> ***Culpability can range along a continuum from destruction intended to make evidence unavailable in litigation to inadvertent loss of information for reasons unrelated to the litigation. Prejudice can range along a continuum from an inability to prove claims or defenses to little or no impact on the presentation of proof. A court's response to the loss of evidence depends on both the degree of culpability and the extent of prejudice***. Even if there is intentional destruction of potentially relevant evidence, if there is no prejudice to the opposing party, that influences the sanctions consequence. And even if there is an inadvertent loss of evidence but severe prejudice to the opposing party, that too will influence the appropriate response, recognizing that sanctions (as opposed to other remedial steps) require some degree of culpability.

688 F.Supp.2d at 613 (emphasis added). Similarly, in *Premier Dealer Serv., Inc. v. Duhon*, Magistrate Judge Roby stated:

> ***Culpability is not established by any bright line test, but rather, analyzed on a case-by-case basis***. Therefore, culpability ranges from bad faith or intentional destruction of evidence by a party, to the gross negligence of a party to preserve evidence once the party knew or should have known that litigation was imminent.

2013 W.L6150602 (E.D. La. 2013) (M.J. Roby) (emphasis added) (internal citation omitted), *citing Yelton v. PHI, Inc.*, 279 F.R.D. 377, 391 (E.D. La. 2011) (M.J. Roby).

Thus, the district courts that have addressed the issue of sanctions for spoliation agree, at the district court level, there should exist a continuum for both degrees of culpable conduct on the part of a defendant and the appropriate remedies to be imposed, and the district court jurisprudence clearly suggests that more culpable conduct on the part of a spoliator warrants a more severe sanction.[82] Thus, this Court agrees the inquiry into the appropriate sanction for spoliation is highly fact-based, hence the need to approach on a case-by-case basis. *See, e.g., Consol. Aluminum Corp*, *supra*, at 339 (". . . the determination of a proper sanction for spoliation, if any, is confined to the sound discretion of the trial judge, and is determined on a case by case basis"), *citing Zubulake IV*, *supra*, at 216.

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[81] Although the court in *Ashton* cites to Fifth Circuit cases, these cases do not contain comprehensive frameworks for the analysis of the issues contained in the instant Ruling.

Recognizing the varying degrees of culpable conduct and level of sanctions that can be imposed, district courts have permitted the parties to put on evidence about the alleged spoliation and let the jury "punish [parties] accordingly." *Wallace v. Ford Motor Co.*, 2013 WL 3288435 (S.D. Miss. 2013) (J. Reeves), *citing Wise*, *supra* at 156 ("A district court has discretion to admit evidence of spoliation and to instruct the jury **on** adverse inferences.")(emphasis added). Additionally, within the context of adverse inferences, courts have crafted *various types* of adverse inference jury instructions, reflecting the various levels of culpable conduct, as follows:

> The court may instruct the jury that "certain facts are deemed admitted and must be accepted as true"; impose a mandatory, yet rebuttable, presumption; or "permit[ ] (but ... not require) a jury to presume that the lost evidence is both

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[82] There can be no question an adverse inference is a severe sanction for spoliation. In *Alcoa,* Magistrate Judge Noland, citing *Zubulake IV*, stated:

> Imposition of an adverse inference instruction has been recognized as a powerful tool in a jury trial since, when imposed, it basically 'brands one party as a bad actor, guilty of destroying evidence that it should have retained for use by the jury.'
>
> The Court in *Zubulake IV* also elaborated on the practical impact of giving an adverse inference instruction. The Court pointed out that the giving of an adverse inference instruction often terminates the litigation in that it is "too difficult a hurdle" for the spoliating party to overcome. When a jury is instructed that it may "infer that the party who destroyed potentially relevant evidence did so 'out of a realization that the [evidence was] unfavorable[' to the other party], the party suffering this instruction will be hard pressed to prevail on the merits." The *Zubulake* court therefore concluded that the adverse inference instruction is an "extreme" sanction that should "not be given lightly."

244 F.R.D. at 340 n.5.

relevant and favorable to the innocent party.

See, e.g., Victor Stanley, Inc. v. Creative Pipe, Inc., 269 F.R.D. 497, 535-36 (D.Md. 2010) (M.J. Grimm).

With the foregoing continuums in mind, this Court will examine the alleged conduct of Takeda and address the fashioning of an appropriate sanction for the destruction of evidence in this case.

The PSC alleges the following evidence establishes bad faith on the part of Takeda as to the established destruction of relevant and beneficial evidence:

- Despite Takeda having actual knowledge of its duty to preserve evidence, files of at least forty-six witnesses were destroyed, deleted or otherwise lost. The files of many of these witnesses played a critical role in the development and marketing of Actos. Witnesses whose files were deleted were at the heart of discussions about bladder cancer and the need to "manage" the bladder cancer risk as a marketing problem.

- The sheer number of custodians whose documents were destroyed after the 2002 Litigation Hold was put into place suggests a deliberate disregard of that hold. Even a company diligently attempting to preserve evidence might mistakenly destroy a small number of files, or even all of the files of a single document custodian. But the wholesale destruction of the files of at least 46 relevant custodians -- *after a litigation hold was instituted* -- cannot be considered accidental. In spite of the 2002 Litigation Hold, Takeda deleted these employees' electronic files, erased hard drives, and destroyed paper files. 38 of the 46 custodians whose files are "missing" were deleted after 2002, when Takeda had issued its 2002 Litigation Hold.

- The scale of the spoliation in this case is further evidence that the documents were destroyed in bad faith. Takeda destroyed documents of relevant custodians on three continents over a period of approximately ten years. This repeated, systemic, and wide-spread destruction can only be the result of a willful and intentional failure to preserve; *i.e.*, a bad faith refusal to preserve evidence in the face of a known obligation to do so.

- In addition to not timely implementing and enforcing litigation holds, Takeda failed to follow its own document retention policies. Takeda admitted this fact in its 30(b)(6) deposition. Takeda also failed to index its backup tapes.

- As part of the spoliation, Takeda made repeated material misrepresentations regarding litigation holds which continue to this date. The misleading June 6, 2013 e-mail from John Martin (which was in specific response to the Special Masters' request) was sent to five additional counsel representing Takeda. The misleading nature of the June 6, 2013 Martin e-mail was compounded by the fact that Takeda allowed the Court to labor under the false impression that the February 2011 reminder was "the" hold until such time as additional disclosures were compelled by a series of more specific questions by the Court and discovery propounded by the PSC. Since that time, Takeda has made a variety of inconsistent disclosures, not always voluntary, and to this date refuses to admit the applicable hold was issued in 2002. At the July 3, 2013 hearing, defense counsel Scott Sayler continued to embrace John Martin's e-mail and the February 2011 date as the applicable litigation hold date.

- On June 14, 2013, eight days after John Martin's June 6, 2013 e-mail, instead of correcting the obvious misrepresentation, Takeda, now through different counsel, sent a "supplement" which again compounds the misrepresentation.

- Instead of the continuing "inquiry" promised by Martin in the June 6, 2013 e-mail (which should have resulted in Takeda admitting the February 15, 2011 was actually a reminder of a much earlier Actos Products Liability Litigation hold), Takeda continued its lack of candor by claiming none of the files of the Japanese custodians were deleted after a legal hold was issued in Japan.

- The decision to designate Dan Regard as the document destruction 30(b)(6) representative as opposed to a witness with direct knowledge of the document destruction and litigation holds is evidence of obfuscation and bad faith.

- Takeda has reversed its position regarding file deletion and inaccessibility. After taking a contrary position, Daniel Regard testified no files had been deleted and it had been Takeda's plan all along to use backup tapes to comply with its hold obligations. Regard also testified it was acceptable to delete files because of backup tapes. However, he could provide no evidence of a written policy to that effect and ignored Corp-B-019, a best practices memorandum and language in the Actos hold itself which contradicted him.

- Takeda did not selectively destroy files pertaining to bladder cancer, while retaining files relating to other problems with Actos, nor did it destroy files of employees whose involvement with Actos was limited to bladder cancer. Rather, it destroyed files of executives with overall Actos responsibility and sales representatives, who would have dealt with *any* Actos defect.

- When Plaintiffs became aware the files of certain document custodians were missing, rather than coming forward with an innocent explanation, Takeda began a campaign of concealment and obfuscation - in short, a cover-up.

The foregoing arguments are supported by evidence in the record. For example, the Court notes Upjohn's correspondence with Mr. Kitazawa, obtained through third-party discovery with Upjohn and not through direct production from Takeda. Again, this correspondence suggests Upjohn withdrew from a development deal with Takeda over issues of **"pioglitazone's margin of safety,"** but that Mr. Kitazawa, acting on behalf of Takeda, nevertheless attempted to shift the Upjohn explanation from their express ***safety concerns*** associated with the drug to the ***efficacy of Actos as a reducer of blood glucose***. To the extent such correspondence evidences a corporate culture embracing attempts to conceal or remove mention of or to underplay expressed safety concerns surrounding the development of Actos in order to move forward with the development marketing of Actos, the Court concludes the fact that Mr. Kitazawa's custodial file was destroyed in the face of the 2002 Litigation Hold is relevant to the issue of bad faith on the part of Takeda.

Also urged by the PSC as an example of Takeda's bad faith is the company's designation of Daniel Regard as Takeda's 30(b)(6) deponent. This Court has reviewed the tortured 30(b)(6) deposition of Daniel Regard and finds a careful reading of the transcript of this deposition reveals Daniel Regard had no personal or first hand corporate knowledge of any Takeda entity's corporate history; was never an employee of any Takeda entity other than as a consultant; and, on its face, his testimony appears rife with deliberate obfuscation and seemingly selective investigation. Daniel Regard had no personal or first hand knowledge of any Takeda entities' document retention systems or destruction of files or retrieval or reconstruction of files and yet, the Court notes Magistrate Judge Hanna, in his discovery order, specifically ordered a Takeda representative be prepared to testify regarding, among other things, inquiry related to document retention systems; inquiry related to the destruction of files at issue; and inquiry into the retrieval and/or reconstruction of the lost or destroyed documents.[83] Indeed, the designation of a Takeda representative with a comprehensive grasp of what was destroyed, how it was destroyed, and why it was destroyed, was considered critical to the parties' and the Court's understanding of how and why such a large amount of crucial evidence in this case was not preserved and to the question of the breadth of discovery to be allowed. In the face of the magistrate judge's order, and in response to the PSC's allegations of wide-ranging and sweeping document destruction in the midst of this complex litigation, Takeda – rather than choosing one or more corporate representative(s) with personal or first hand knowledge of Takeda's document retention policies, litigation hold procedures, and the interplay between the two - chose to retain *one outside electronic discovery consultant* to testify to the important topics of these issues. Although perhaps not in and of itself violative of Rule 30(b)(6), when one looks to the actual testimony given, as well as to Magistrate Judge Hanna's multiple orders, the PSC's argument cannot be said to be without merit. The PSC argues, and this Court cannot fully disagree, that the very selection of Mr. Regard as Takeda's 30(b)(6) designee in the face of Magistrate Judge Hanna's orders reflected the tone of Takeda's less-than-desirable historical approach to the issues raised in the instant motion. Against this backdrop, the Court takes a dim view of Takeda's argument that it complied with the spirit of the magistrate judge's 30(b)(6) order and will address that argument when the Court addresses the PSC's argument as to Fed.R.Civ.P. Rule 37 sanctions.

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[83] *See* "Ruling on Motion," Doc. 2992, at p. 9.

Nonetheless, Daniel Regard's actual testimony is directly relevant to the issue now at hand. For example, despite testifying he "conducted dozens of employee interviews, went on site visits, and reviewed numerous Takeda documents and policies in preparation for the deposition," it is clear from a review of the deposition transcript and specific interviews conducted by Mr. Regard that Mr. Regard did not interview many of the pivotal Takeda employees who might have had knowledge as to certain pivotal document retention issues at hand. For example, it is not at all clear from the record that Mr. Regard spoke to the relevant IT employees at the Takeda various entities, and his testimony does not illustrate a strong grasp of the IT procedures and their interplay with litigation hold policy at the company.

Furthermore, although his attached list of witnesses interviewed and documents reviewed denotes he interviewed Stacey Calahan, Assistant General Litigation Counsel for Takeda Pharmaceuticals USA, Inc. - whose "Declaration" Takeda now submits as part of Takeda's opposition to this motion - it does not appear Mr. Regard discussed with Ms. Calahan the extremely relevant issue of the evolution of Takeda's document retention polies *vis-a-vis* the specific litigation holds at issue in this litigation.[84] Indeed, it is clear from the deposition transcript there were a number of important issues related to the litigation holds that Mr. Regard simply did not question Ms. Calahan about, including the discrepancy between the two litigation hold dates provided to the PSC on June 6, and 14, 2013 by Takeda and yet, Takeda now submits Ms. Calahan's "Declaration" to address this very issue. As Mr. Regard had *no personal knowledge* or *first hand corporate knowledge* concerning these issues himself – having never worked for Takeda other than as a consultant and having only been retained to answer questions at Takeda's 30(b)(6) deposition - the Court is perplexed as to how Mr. Regard could have been expected to provide definitive and comprehensive answers to the many questions specifically ordered by the magistrate judge and, in fact, a careful review of his deposition shows that in large part, he did not.

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[84] This Court notes, again, the portion of Mr. Regard's deposition where he acknowledges it did not occur to him to ask Ms. Calahan certain vitals questions, as follows:

> Q: Okay. Well, the point we're getting to here is, the February hold, the February 2011 hold that Ms. Calahan distributed –

Even more important, as noted, in response to the instant motion, Takeda has submitted the "Declaration" of Ms. Calahan under 28 U.S.C. §1746.[85] In this "Declaration," Ms. Calahan

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A: Yes, sir.

Q: – the language changed significantly, did it not, from the 2006 and 2007 version, which were the same?

A: It looks to be very different, yes.

Q: Okay. So why – when you talked to Ms. Calahan, when she said she was – this was just some sort of refresh unrelated to any bladder cancer or any particular event, why did she completely redraft the hold?

A: I did not ask her that question.

Q: Why not? Why didn't you ask her that?

A: It didn't occur to me at the time to ask her.

See Deposition of Daniel Regard, at pp. 782-83.

[85] 28 U.S.C. §1746 states:

§1746. Unsworn declarations under penalty of perjury does not indicate her personal knowledge of any of the facts contained therein, but declares under penalty of perjury that the "Declaration" is true and correct to the best of her knowledge and yet, her employment time with Takeda belies personal knowledge of many of those self-serving declarations.[86] As to the efficacy of the procedural choice of Takeda in attaching the foregoing "Declaration" to its opposition brief, this Court notes the "Declaration" contains, it would appear, self-serving declarations more in the nature of expert testimony as to the law - particularly in the section of the "Declaration" entitled "Conclusions" - content not appropriate for such a declaration. There is no indication Ms. Calahan's "Conclusions" were, or given her start date with Takeda, could have been conveyed to Takeda contemporaneously with Takeda's choices *vis-a-vis* the earlier litigation holds. Rather, Ms. Calahan's "conclusions" appear to be hindsight quasi-expert opinions as to the law, which this Court finds to be of no benefit to the

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> Wherever, under any law of the United States or under any rule, regulation, order, or requirement made pursuant to law, any matter is required or permitted to be supported, evidenced, established, or proved by the sworn declaration, verification, certificate, statement, oath, or affidavit, in writing of the person making the same (other than a deposition, or an oath of office, or an oath required to be taken before a specified official other than a notary public), such matter may, with like force and effect, be supported, evidenced, established, or proved by the unsworn declaration, certificate, verification, or statement, in writing of such person which is subscribed by him, as true under penalty of perjury, and dated, in substantially the following form:
>
> (1) If executed without the United States: "I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date).
>
> (Signature)".
>
> (2) If executed within the United States, its territories, possessions, or commonwealths: "I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date).
>
> (Signature)".

[86] This Court notes Ms. Calahan's tenure at Takeda would not grant her individual knowledge before July 2007, when she began her employment with Takeda Pharmaceuticals U.S.A., Inc., and thus, she, too, lacks the necessary personal or first hand corporate knowledge to fully enlighten this Court to matters predating July of 2007.

Court.

As this Court has noted in other contexts, it is for this Court to determine the law, its application, and, as to spoliation, reach its conclusions as to whether a violation has occurred. The Court is not in need of any "quasi-expert," conclusions as to what the law should be. Consequently, Ms. Calahan's hindsight conclusion(s) as to how she might or might not see the law applying, with no indication she was even present at many of the times at issue, is of no moment. Furthermore, if this Court were to parse out Ms. Calahan's opinion testimony from that about which she could and presumable does have personal knowledge, the "Declaration" continues to perplex the Court. From a procedural standpoint, to the extent the "Declaration" was put forth as an *affidavit*, the document is clearly self-serving, and much is not based upon her personal or corporate knowledge, and, again, appears designed to offer hindsight quasi-expert opinion for events of which the affiant has no personal knowledge. To the extent the "Declaration" is not in the nature of an affidavit, then the "Declaration" appears to be only a self serving declaration rife with opinion and containing little fact based upon actual personal knowledge.

Furthermore, this Court specifically notes additional problems with the "Declaration." First, Ms. Calahan states she began working for Takeda Pharmaceuticals U.S.A., Inc. in July 2007. Yet, the 2002 Litigation Hold about which Ms. Calahan "testifies" by way of her "Declaration" was written and implemented five years earlier – in 2002 – and consequently, Ms. Calahan can have no personal knowledge regarding the implementation of this hold and she gives no factual basis for her statements as to the nature of the 2002 hold. It, also, is not clear how Ms. Calahan might have obtained knowledge of the information about which she declares (again, events that occurred five years before her employment with Takeda USA began). Furthermore, her declarations about events that occurred in 2002 patently cannot be personal, as Ms. Calahan did not work for the company in 2002. Moreover, despite authoring the "Declaration" and being held out by Takeda as someone having knowledge about the events of which she declares, as noted herein, *Takeda did not designate Ms. Calahan as one of its corporate representatives at the 30(b)(6) deposition* for these very same issues, rather, designated Mr. Regard, but thereafter presents her by way of a blatant self-serving declaration as the person having that very information. Of course, under a 30(b)(6) deposition, rarely does the person responding have *personal knowledge* as to all he or she testifies, but rather, has *corporate knowledge* of the subjects, often by virtue of their position within the corporation. However, Ms. Calahan's "Declaration" is not being put forth pursuant to a 30(b)(6) inquiry, rather, is being put forth in opposition of the PSC's motion as one who has personal knowledge of the events at issue - and yet, she can have no such *personal* knowledge of events preceding 2007. All of the foregoing, however, begs the question: If Takeda holds Ms. Calahan out in the "Declaration" as its leading affiant with respect to the issue of litigation holds, why was Ms. Calahan not designated as one of the company's corporate representatives for purposes of the 30(b)(6) and Magistrate Judge Hanna's Order? Perhaps the question is answered when one considers that Ms. Calahan's "Declaration" reads more like a self-serving deposition but one *which grants no opportunity for cross-examination.* Furthermore, as a fact witness, this Court finds Ms. Calahan's attestations – when read in the light of Mr. Regard's deposition transcript – much like Mr. Regard's testimony, raise more questions than they answer. Indeed, the Declaration supports this Court's determination that Takeda, in fact, issued a litigation hold; that litigation hold was "refreshed;" those litigation holds are the best evidence of their content and application; and a reading of those holds shows the holds were in no way limited to any one potential malady. In fact, Ms. Calahan states in her Declaration that "[i]nstructions for complying with legal holds are generally provided within the legal holds themselves." Ms. Calahan is correct; the 2002 Litigation Hold does, in fact, contain three express instructions, under the section entitled "Action Steps," as follows:

> Please **interpret this directive in its broadest sense** to prevent the deletion or destruction of any recorded information and date relating in any way to Actos.
>
> Please take steps immediately to preserve such documents and data within your department.
>
> Please distribute this memo to members of your group and advise them of the importance of following these instructions.[87]

Thus, the express language of the 2002 Litigation Hold - which according to Ms. Calahan's was "refreshed" multiple times up to and including 2011 - instructs the recipients to construe the hold as broadly as possible, and contains no limitations as to maladies, belying all of Ms. Calahan's attestations contained within her "Declaration" that the 2002 Litigation Hold should be or was to have been narrowly construed. That Ms. Calahan is now urging this Court to read into the 2002 Litigation Hold limitations that are not found within the language or instruction of the holds is not lost on the Court and, it would seem, acts to support the PSC's argument.

As noted, in support of its position, Takeda primarily submits Ms. Calahan's

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[87] *See* 2002 Litigation Hold, attached as Exhibit 13 to the instant motion.

"Declaration" and Daniel Regards' depositions, as well as his affidavit.[88] Finally, the Court notes that in choosing Mr. Regard, and submitting Ms. Calahan' "testimony" by "Declaration," the PSC's argument that Takeda appears to have chosen to attempt to insulate Takeda from questioning is persuasive. Indeed, Mr. Regard was asked at his deposition why he did not question Ms. Calahan about the core issue at play and he simply responded it did not occur to him to do so. It is, also, not lost on this Court that the PSC argues *Takeda* chose the individuals whom Mr. Regard interviewed, and thus, controlled Mr. Regard's access to critical information regarding the very topics upon which he was designated to testify and additionally, that Takeda and Ms. Calahan selected the content of her "Declaration." And, after full review of Mr. Regard's tortured deposition, this Court cannot help but question Mr. Regard's testimony that he was comprehensively prepared to answer questions about the very critical issues outlined by the 30(b)(6) notice and Magistrate Judge Hanna's order, but more importantly, must question Takeda's arguments that it acted in good faith in designating Mr. Regard to speak for Takeda at the deposition in the face of the discovery dispute and Magistrate Judge Hanna's orders.

In addition to the noted "evidence" presented and arguing it had no duty to preserve evidence before 2011, Takeda vehemently challenges the assertions of the PSC, that Takeda's conduct reflects sufficient culpable intent to support sanctions, arguing it has steadfastly maintained good faith in both its document retention policies and its participation in discovery in this matter and points to the massive number of documents actually presented. Again, in a case of this magnitude extending over as many years as this one, and in this age of technology, one must expect a plethora of discoverable documents and commends Takeda for its laudable participation in discovery. However, the number of documents produced cannot fully justify the widespread failure to preserve large swaths of Actos - related documents generated and held by so may high-ranking officials. After reviewing the arguments of the parties, the breadth of the "lost" information, and the job titles of those whose files were lost, as well as the Upjohn incident, when coupled with the ever-evolving arguments made by Takeda to the magistrate judge and the seemingly internally inconsistent testimony of Daniel Regard as to "backup tapes," as well as Ms. Calahan's "Declaration," this Court, admittedly, has grave concerns about Takeda's pure intent.

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[88] Both parties to this motion submitted expert opinion evidence by way of declaration. (*See* Plaintiffs' Exhibit 7 (Declaration of Darrell Long, expert in storage systems research and computer science generally), and Defendants' Exhibit 6 (Declaration of Daniel L. Regard, II, expert in electronic technology and document production in a litigation context)). This Court has not discussed or considered either declaration, in the context of this motion, for two very important reasons. First, neither complies with the requirements of Fed.R.Civ.Pro. 26(b) and F.R.E. 702. Second, the expert opinions proffered are of very limited assistance to this Court under these circumstances, Dr. Long's opinions about the sufficiency of Takeda's computer storage systems have not become relevant because this Court's ruling does not turn on any finding about Takeda's computer storage system. Similarly, the considered opinion of Takeda's professional consultant that the company has done a "swift, broad and effective" job of preserving documents seemingly is directed at replacing this Court's opinion with his own; an occurrence which would be wholly inappropriate.

Considering the foregoing, and after review of all of the evidence presented by the PSC, and the evidence and arguments presented by Takeda, this Court finds the PSC has carried its burden to establish both beneficial relevance and prejudice and that the PSC has made a strong and persuasive showing from the evidence of a "culpable state of mind" on the part of Takeda in its destruction of evidence. Nevertheless, this Court, at this juncture, stops short of concluding the PSC has demonstrated sufficient bad faith to support the full breadth of onerous sanctions requested. Rather, as sister courts have permitted, this Court determines it will allow all evidence of bad faith to go to the jury, and thereafter, will devise a jury instruction to be given to the jury on this point after hearing all evidence presented by each side.[89] After having heard all the evidence, this Court will, at the final charge conference, determine what specific charge will be given to the jury as to what inference, if any, they might employ.[90]

V. Determination

This Court has found Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals America, Inc., and Takeda Japan had a duty to preserve "any and all documents and electronic data which discuss, mention or relate to Actos," as of implementation of the 2002 Litigation Hold, and that Takeda Europe had the same duty as of 2006. This Court has found the same Takeda entities breached that duty by the destruction of documents and electronic data after those dates and that the information destroyed is deemed relevant to proof of legal issues now before this Court and, likely, beneficial to plaintiffs' case, and, therefore, the absence of which is, likely, prejudicial to the plaintiffs. This Court does not, at this juncture - reserving that determination until after this Court has heard all evidence at trial - however, make a determination as to the full extent of culpability of Takeda in that breach of their duty, and therefore, the nature or strength of the instruction to be given the jury.

The PSC, also, requests sanctions which begin with the draconian default judgment and include, in the alternative, "a combination . . . of cost shifting, a fine, an adverse inference jury instruction, restoration of deleted files and attorneys' fees and costs." The Court will not enter a default judgment against Takeda, as the Court believes such a sanction is too severe. Therefore, this request is DENIED. Furthermore, this Court finds the requests for cost-shifting, a fine, and the restoration of deleted files are better addressed under the purview of Fed.R.Civ.P. 37, or as to spoliation after all evidence has been heard at trial. Therefore, this Court expressly DEFERS ruling upon the request for cost shifting or fines, as well as the request for sanctions pursuant to Rule 37 and will await the unfolding trial phase, without prejudice to Plaintiffs' right to raise the issue(s) for immediate determination at any time they might deem appropriate. However, counsel are cautioned that the requested remedy of "restoration of deleted files" -- where possible -- with cost-shifting and attorneys' fees and costs are well within the Court's consideration and authority under both Rule 37 and spoliation.

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[89] This Court is also mindful that a majority of the evidence related to spoliation will likely be relevant to other issues in the trial, particular the issue of punitive damages, and, thus, will not inordinately delay the trial of this matter by virtue of its presentation.

[90] *See* fn 88.

As noted, the PSC argues sufficient bad faith and culpable intent on the part of Takeda, which they argue cannot adequately be dealt with under the Rules (*i.e.*, Takeda's conduct before this litigation began), and request(s) sanctions within the inherent powers of this Court. This Court agrees with my sister Courts, "whether preservation or discovery conduct is acceptable in a case depends **on what is reasonable**." *Rimkus*, 688 F.Supp. 2d at 613 (emphasis added). Under the circumstances of this case, the *reason* for the destruction of evidence is vehemently contested and in no small part depends upon the *explanation* for the absence of the evidence, rather than testimony as to whether that absence exists. This Court notes its determination is exasperated by Takeda's evidence presented in opposition to the PSC's motion, i.e., its choice to provide a witness to respond for it in its 30(b)(6) deposition who was not then, and at no time had been, an employee of any of the Takeda entities (other than to serve as a consultant) and whose corporate "investigation" appears cursory at best and thus, who could shed precious little, if any, relevant light upon the reasons for the actual destruction of files which occurred at

Takeda and the litigation holds at play and Takeda's choice to provide a self-serving "Declaration," from one whose employment history belies her possible personal knowledge and, therefore, which provides precious little relevant factual information to this Court as to the issues at hand. It is not lost on this Court these decisions rested solely with Takeda. Nonetheless, the fact remains this Court finds itself on the eve of the first bellwether trial without persuasive, credible, and informed explanation as to why the destruction of files actually occurred. Nonetheless, and in the face of such absence of relevant information, this Court must determine what is "reasonable" given the unique circumstances at hand, while bearing in mind the remedy must be tailored to the conduct and should impose the least onerous sanction available that addresses the level of conduct at hand. Nonetheless, based upon the evidence and argument presented by both sides, this Court finds it wholly reasonable to allow the jury to hear all evidence and argument establishing and bearing on the good or bad faith of Takeda's conduct and after hearing all such evidence, the instruction to be given the jury in a manner congruent with that evidence.

This Court is not unmindful of the gravity of the requests made, and is of the opinion the Court can benefit from hearing and seeing all of the evidence at trial before determining what actual instruction should be given the jury; that determination to be made at the final charge conference of the first bellwether trial.

The PSC, also, requests fines and attorneys' fees. Again, this Court is of the opinion it will benefit from hearing the testimony concerning this issue at trial before determining if any further sanction is appropriate, however, invites the PSC to raise the issue of fines or attorneys' fees after this Court has had benefit of all testimony at the first bellwether trial.

VI. CONCLUSION

This Court will, for the full reasons given above, allow all evidence of and relating to Takeda's conduct as to documents and electronic data destruction to go before the jury and will, after having heard all evidence, determine what instruction to give the jury. Additionally, the request for a default judgment is DENIED, and this Court DEFERS on the PSC's request for attorneys' fees and costs until having had benefit of hearing trial testimony.

Additionally, this Court DEFERS on the Rule 37 determination until after the bellwether trial process is completed.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 27 day of January, 2014.

REBECCA F. DOHERTY
UNITED STATES DISTRICT JUDGE